Rehabilitation versus surgical reconstruction for non-acute anterior cruciate ligament injury (ACL SNNAP): a pragmatic randomised controlled trial

BEARD, D.J., DAVIES, L., COOK, J.A., STOKES, J., LEAL, J., FLETCHER, H., ABRAM, S., CHEGWIN, K., GRESHON, A., JACKSON, W., BOTTOMLEY, N., DODD, M., BOURKE, H., SHIRKEY, B.A., PAEZ, A., LAMB, S.E., BARKER, K., PHILLIPS, M., BROWN, M., LYTHE, V., MIRZA, B., CARR, A., MONK, P., MORGADO AREIA, C., O'LEARY, S., HADDAD, F., WILSON, C., PRICE, A., EMSLEY, R., PEAT, George <http://orcid.org/0000-0002-9008-0184>, SNOW, M., CAMPBELL, M., HOWELL, T., JOHNSON, H., MCDONNELL, S., PINKNEY, T., WILLIAMS, M., CAMPBELL, H., DAVIES, J., LI, J., BAGG, C., HAYWOOD, L., NICHOLSON, A., RICHES, J., SYMONS, S., VERTUE, M., AL MOUAZZEN, L., BRAY, R., CLARK, D., COULTHARD, J., HOLLAND, T., HOWELLS, N., JONES, A., KAPUR, R., KISZELY, A., KRISHNAN, H., MACDONALD-TAYLOR, K., MANARA, J., MURRAY, J., NEGRUT, C., PAI, V., PORTEOUS, A., PUTNIS, S., ROBINSON, J., RUPASINGHE, S., SELVARATNAM, V., SMITH, J., SMITH, N., STEVENS, J., TAYLOR, C., THEODORIDES, A., VETHARAJAN, N., VINT, H., YOUNG, L., BULLOCK, S., COOK, R., DODDS, A., FREEMAN-HICKS, A., HILLOUT, P., CORNELL, T., COUTTS, A., DEAN, S., DEVOOGHT-JOHNSON, N., FERRELL, E., FLETCHER, E., HALL, C., KENT, B., KESSLY, S., KINCAID, R., LAZIZI, M., MOSTAFA, A., NISBETT, T., POWELL, T., RIDDLESTONE, P., ROBERTON, A., SUMMERS, J., WHITBREAD, L., WROATH, B., FENLON, E. and HALL, A.

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Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Beard DJ, Davies L, Cook JA, et al. Rehabilitation versus surgical reconstruction for non-acute anterior cruciate ligament injury (ACL SNNAP): a pragmatic randomised controlled trial. *Lancet* 2022; **400:** 605–15.

Appendix: Comparison of two management strategies for non-acute Anterior Cruciate Ligament (ACL) injury: Rehabilitation versus surgical Reconstruction (ACL SNNAP Trial)

Statistical Analysis Additional Details

Adjusted and unadjusted analyses were carried out on the intention to treat (ITT), conservative per protocol (PPC) and pragmatic per protocol (PPP) populations using linear regression. Complier Average Causal Effect (CACE) analysis assessing compliance to receipt of surgery or not were also carried out using instrumental variable regression. The impact of missing data at the participant level was explored via sensitivity analyses for the primary outcome using the rctmiss package in Stata. A pattern-mixture model was used to extend the adjusted linear regression model used for the primary outcome analysis, in order to show graphically the difference in treatment effect for each treatment arm if different mean values are assumed for the missing data. Subgroup analyses of gender, baseline KOOS4 scores, age and baseline Tegner Activity Scores were carried out using treatment-subgroup interactions and interpreted as exploratory analyses.

A secondary analysis of the primary outcome was also performed on the ITT population using an area under the curve (AUC) approach. The treatment estimates obtained from a mixed model at each timepoint (baseline, 6 months, 12 months, 18 months) were used to calculate the AUC. The model included repeated measures of the KOOS4 score (level 1), nested within participants (level 2) and adjusted for recruitment site as a random effect (level 3). A treatment by time-point interaction was also included in the model. Please also see the published study protocol and statistical analysis plan.[18,24]

Supplementary Table S1: List of sites

Participants were recruited between 1st February 2017 and 12th April 2020 from 29 NHS secondary care hospitals from across the UK. Each site is listed below:

Abertawe Bro Morannwg University Health Board, Morriston Hospital, Swansea
Betsi Cadwaladr University Health Board, North Wales
Betsi Cadwaladr University Health Board, Wrexham
Countess of Chester Hospital NHS Foundation Trust
Frimley Health NHS Foundation Trust
Frimley Health NHS Foundation Trust, Wexham
Gloucestershire Hospitals NHS Foundation Trust
Great Western Hospitals NHS Foundation Trust, Swindon
Kings College Hospital NHS Foundation Trust
Leeds Teaching Hospitals NHS Trust
Manchester University NHS Foundation Trust
North Bristol NHS Trust
North West Anglia NHS Foundation Trust, Peterborough
Oxford University Hospitals NHS Foundation Trust
Royal Berkshire NHS Foundation Trust
Royal Cornwall Hospitals NHS Trust
Royal Surrey County Hospitals NHS Foundation Trust
Salisbury NHS Foundation Trust
Sheffield Teaching Hospitals NHS Foundation Trust
Sherwood Forest Hospitals NHS Foundation Trust, Sutton in Ashfield
Solent NHS Trust, Portsmouth
Stockport NHS Foundation Trust
Taunton and Somerset NHS Foundation Trust, Musgrove
The Mid Yorkshire Hospitals NHS Trust
University Hospitals Coventry and Warwickshire NHS Trust
University Hospitals of Leicester
Warrington and Halton Hospitals NHS Foundation Trust
Wrightington, Wigan and Leigh NHS Foundation Trust
Yeovil District Hospital NHS Foundation Trust

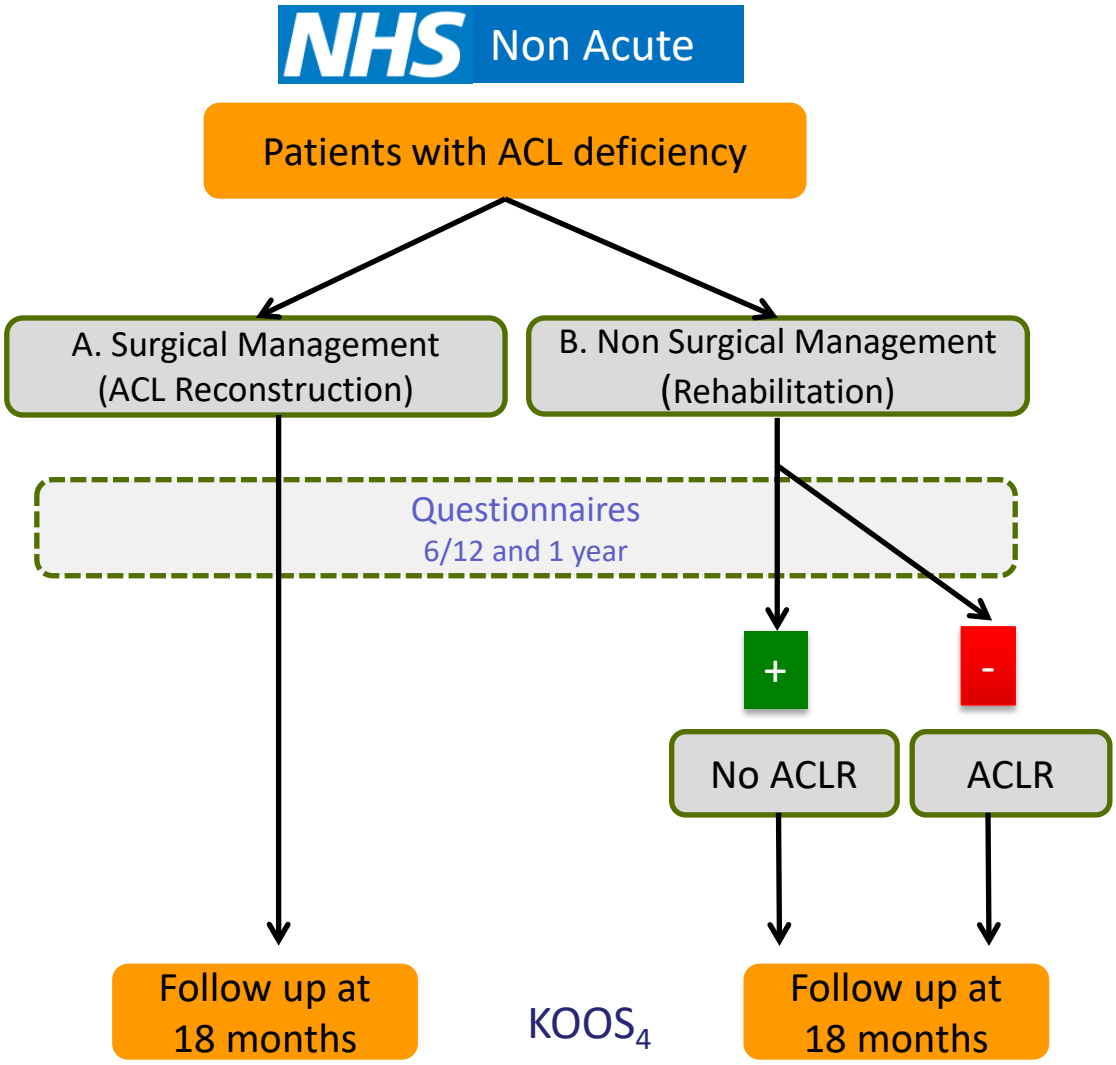

Figure S1: Study design schematic showing management pathways with expected potential interventions.

Supplementary Table S2: Detailed breakdown of screening data

Total screened	**1403**
Total not eligible (reasons)	**602**
Other	159
Pregnancy	2
Inflammatory arthropathy	3
Grade 3 MCL/LCL injury	55
Grade 3 MCL/LCL injury + Other	1
Grade 3 or 4 on KL scale	17
Grade 3 or 4 on KL scale + Other	1
Meniscal pathology	148
Meniscal pathology + Other	3
Meniscal pathology + Grade 3 MCL/LCL injury	3
Previous knee surgery	91
Previous knee surgery + Grade 3 or 4 on KL scale	2
Previous knee surgery + Meniscal pathology	3
Previous knee surgery + Meniscal pathology + Grade 3 MCL/LCL injury	1
Previous knee surgery + Meniscal pathology + Grade 3 or 4 KL scale	1
Acute injury	81
Acute injury + Other	9
Acute injury + Grade 3 MCL/LCL injury	3
Acute injury + Meniscal pathology	15
Acute injury + Meniscal pathology + Grade 3 MCL/LCL injury	1
Acute injury + Meniscal pathology + Grade 3 or 4 KL scale	1
Acute injury + Previous knee surgery	1
Grade 3 MCL/LCL injury + Previous knee surgery	1
Total eligible to be randomised	**801**
Total eligible but not participating (reasons)	**485**
Patient preferred surgery	276
Patient preferred physiotherapy	115
Other	67
No reason given	27
Total randomised	**316**

Supplementary Table S3: Stratification factors according to allocated intervention groups

	Surgical Reconstruction(N=156)		Rehabilitation (N=160)		Total (N=316)	
	n	**%**	**n**	**%**	**n**	**%**
KOOS Category at randomisation						
High (≥ 30)	116	74	124	78	240	76
Low (< 30)	40	26	36	23	76	24
Centre						
Bristol	2	1	4	3	6	2
Cheltenham	2	1	1	1	3	1
Cornwall	1	1	1	1	2	1
Countess of Chester	1	1	2	1	3	1
Coventry	3	2	3	2	6	2
Frimley	1	1	0	0	1	<1
Kings College	8	5	9	6	17	5
Leeds	3	2	3	2	6	2
Leicester	9	6	7	4	16	5
Manchester	5	3	5	3	10	3
MidYorks	3	2	4	3	7	2
Musgrove	2	1	3	2	5	2
North Wales	0	0	1	1	1	<1
Oxford	21	13	19	12	40	13
Peterborough	6	4	6	4	12	4
Royal Berkshire	1	1	1	1	2	1
Royal Surrey	10	6	10	6	20	6
Salisbury	7	4	7	4	14	4
Sheffield	2	1	1	1	3	1
Solent/Portsmouth	3	2	4	3	7	2
Stockport	1	1	0	0	1	<1
Sutton in Ashfield	6	4	7	4	13	4
Swansea	19	12	20	13	39	12
Swindon	8	5	9	6	17	5
Warrington	11	7	11	7	22	7
Wexham Park	14	9	13	8	27	9
Wrexham	3	2	4	3	7	2
Wrightington	2	1	2	1	4	1
Yeovil	2	1	3	2	5	2

Supplementary Table S4: Reasons for injury according to allocated intervention groups

	Surgical Reconstruction(N=156)		Rehabilitation (N=159)		Total (N=315)	
	n	**%**	**n**	**%**	**n**	**%**
American Football	3	12	0	0	3	1
Athletics/Running	4	3	0	0	4	1
Basketball	1	1	2	1	3	1
Car/Cycle/Motorcycle RTA	9	6	8	5	17	5
Cricket	1	1	1	1	2	1
Dancing	3	2	3	2	6	2
Football	56	36	63	40	119	38
Hockey	0	0	1	1	1	<1
Horse Riding	2	1	1	1	3	1
Jumping	1	1	1	1	2	1
MISC TRAUMA	1	1	0	0	1	<1
Martial Arts/Wrestling	3	2	4	3	7	2
Netball	6	4	11	7	17	5
Rugby	16	10	17	11	33	10
Skiing/Snowboarding	15	10	15	9	30	9
Skydiving	1	1	0	0	1	<1
Trampolining	3	2	6	4	9	3
Trip/Fall/Twisting Injury (non-specific sport)	26	17	22	14	48	15
Ultimate Frisbee	1	1	0	0	1	<1
Unknown mechanism	0	0	1	1	1	<1
Volleyball	1	1	0	0	1	<1
Water sports	1	1	0	0	1	<1
Weight training	0	0	1	1	1	<1
Missing	2	1	3	2	5	2

Supplementary Table S5: Baseline characteristics of participants according to allocated intervention groups

	Surgical Reconstruction (N=156)	Rehabilitation (N=159)	Total (N=315)
KOOS pain score at baseline, n, mean (SD)	62.9 (20.5)	59.4 (19.6)	61.1 (20.1)
KOOS symptoms score at baseline, n, mean (SD)	57.1 (21.8)	54.3 (19.3)	55.7 (20.5)
KOOS ADL score at baseline, n, mean (SD)	67.8 (22.8)	67.9 (21.3)	67.8 (22.0)
KOOS sport/rec score at baseline, n, mean (SD)	34.6 (27.1)	33.4 (26.5)	34.0 (26.7)
KOOS QOL score at baseline, n, mean (SD)	28.3 (20.4)	26.3 (19.1)	27.3 (19.7)
KOOS5 score at baseline, n, mean (SD)	50.1 (19.8)	48.3 (18.1)	49.2 (19.0)
Tegner Activity level before injury at baseline, n (%)			
Level 0	0 (0)	0 (0)	0 (0)
Level 1	1 (1)	1 (1)	2 (1)
Level 2	0 (0)	2 (1)	2 (1)
Level 3	3 (2)	12 (8)	15 (5)
Level 4	14 (9)	9 (6)	23 (7)
Level 5	21 (13)	17 (11)	38 (12)
Level 6	22 (14)	20 (13)	42 (13)
Level 7	44 (28)	35 (22)	79 (25)
Level 8	10 (6)	9 (6)	19 (6)
Level 9	26 (17)	42 (26.6)	68 (22)
Level 10	15 (10)	11 (7)	26 (8)
Tegner Activity level today at baseline, n (%)			
Level 0	11 (7)	13 (8)	24 (8)
Level 1	28 (18)	40 (25)	68 (22)
Level 2	37 (24)	33 (21)	70 (22)
Level 3	43 (28)	41 (26)	84 (27)
Level 4	23 (15)	20 (13)	43 (14)
Level 5	6 (4)	6 (4)	12 (4)
Level 6	3 (2)	2 (1)	5 (2)
Level 7	4 (3)	2 (1)	6 (2)
Level 8	0 (0)	1 (1)	1 (<1)
Level 9	0 (0)	1 (1)	1 (<1)
Level 10	1 (1)	0 (0)	1 (<1)
Tegner Activity level you expect to return to at baseline, n (%)			
Level 0	0 (0)	0 (0)	0 (0)
Level 1	0 (0)	2 (1)	2 (1)
Level 2	1 (1)	2 (1)	3 (1)
Level 3	6 (4)	7 (4)	13 (4)
Level 4	11 (7)	13 (8)	24 (8)
Level 5	23 (15)	20 (13)	43 (14)
Level 6	24 (15)	27 (17)	51 (16)
Level 7	42 (27)	37 (23)	79 (25)

	Surgical Reconstruction (N=156)	Rehabilitation (N=159)	Total (N=315)
Level 8	10 (6)	11 (7)	21 (7)
Level 9	28 (18)	31 (20)	59 (19)
Level 10	11 (7)	8 (5)	19 (6)
ACL QOL subscale symptoms and physical complaints at baseline, n, mean (SD)	42.4 (23.2)	39.9 (20.3)	41.2 (21.8)
at baseline, n, mean (SD)	37.5 (26.7)	34.4 (24.9)	36.0 (25.8)
ACL QOL subscale recreational activities and sport participation at baseline, n, mean (SD)	14.8 (15.9)	12.8 (14.2)	13.8 (15.1)
ACL QOL subscale lifestyle at baseline, n, mean (SD)	26.7 (22.8)	22.0 (19.4)	24.3 (21.3)
ACL QOL subscale social and emotional at baseline, n, mean (SD)	26.6 (20.4)	21.6 (18.0)	24.1 (19.4)

Notes: One patient randomised to the rehabilitation arm and requested that their outcome data has not been used for the trial and is not reported in the tables. They have been excluded from this table. 156 and 159 observations are reported for the surgical management and non-surgical management groups except for ACL QOL subscale symptoms (156 and 157 observations respectively), ACL QOL subscale recreational activities and sport participation (155 and 156 observations respectively), ACL QOL subscale lifestyle (155 and 156 observations respectively), ACL QOL subscale social and emotional (155 and 156 observations respectively).

Supplementary Table S6: Time to surgery for those who received surgery by 18th months

	Surgical Reconstruction (N=110)	Rehabilitation (N=62)	Total (N=172)
	median (IQR)	**median (IQR)**	**median (IQR)**
Time to surgery (days)	113 (66,158)	237 (156,341)	135 (82, 235)

Note: Exact date of surgery was unavailable for 6 (3 in each randomised group) who underwent surgery in a private hospital.

Supplementary Table S7: Complier average causal effect (CACE) analysis of KOOS4 score at 18 months

	Surgical Reconstruction - Rehabilitation
	CACE Mean difference (95% CI) [P-value]
KOOS4 CACE Treatment Effect, adjusted for baseline KOOS4 and recruitment site	22.8 (6.9, 38.8) [0.0051]
KOOS4 CACE Treatment Effect, unadjusted	25.0 (9.4, 40.5) [0.0017]

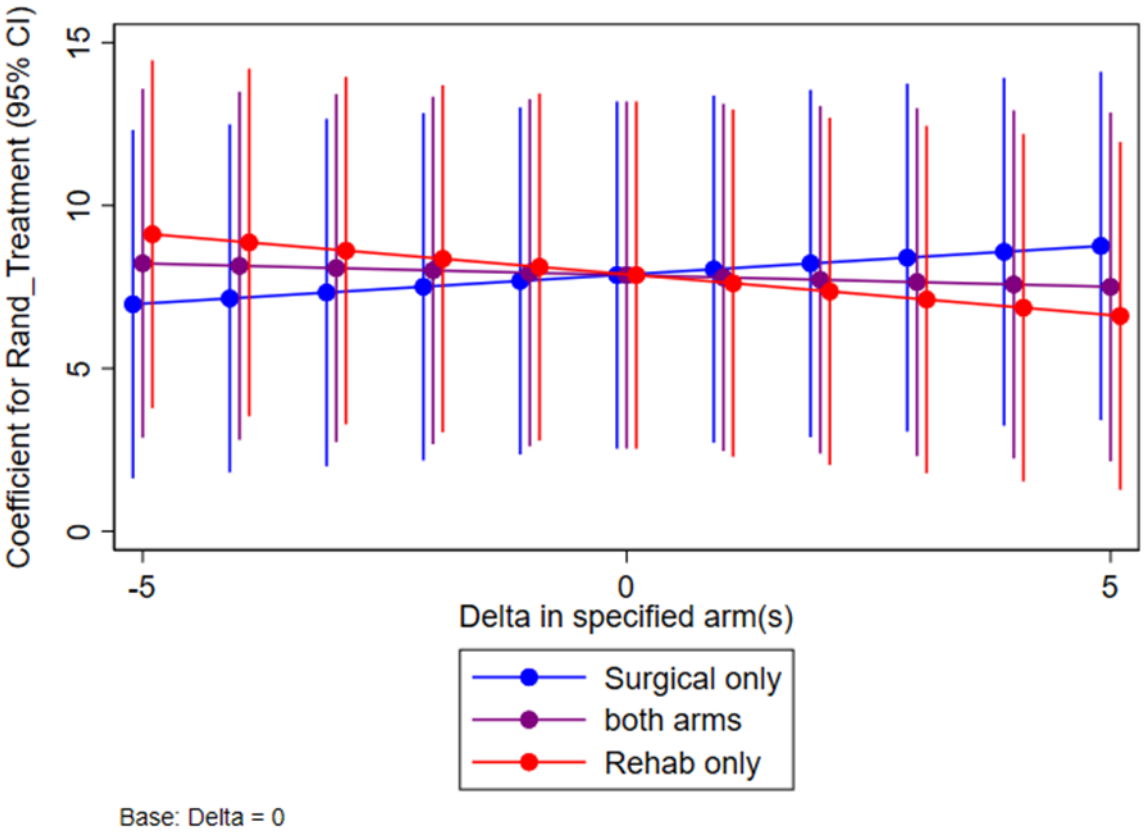

Figure S2: rctmiss sensitivity analysis for 18 months KOOS4 (primary outcome)

Supplementary Table S8: Exploratory subgroup analyses of sub-group factors at 18 months

Subgroup	Subgroup Strata	Mean difference (95% CI)	Interaction Effect (95% CI)	Interaction P-value
Gender	**Male (n=209)**	8.1 (-0.4, 16.7)	0.5 (-15.4, 16.4)	0.95
	Female (n=107)	7.6 (-2.9, 18.2)		
KOOS4 Scores	**Low (n=76)**	4.8 (-2.5, 12.0)	-11.8 (-30.7, 7.0)	0.21
	High (n=240)	16.6 (1.6, 31.6)		
Age	**Less than 40 (n=236)**	8.0 (-4.7, 20.7)	0.3 (-12.2, 12.8)	0.96
	40 and over (n=80)	7.7 (3.1, 12.3)		
Tegner Activity Scale	**Moderate/light activity (n=42)**	6.4 (0.8, 12.0)	-9.1 (-28.7, 10.5)	0.35
	High activity (n=274)	15.5 (-3.2, 34.2)		

Supplementary Table S9: Secondary AUC analysis of primary outcome (ITT population)

	Surgical Reconstruction	Rehabilitation	Surgical Reconstruction - Rehabilitation
	mean (SD)	**mean (SD)**	**Mean difference (95% CI) [P-value]**
KOOS4 AUC	61.7 (17.2)	57.6 (17.7)	4.1 (0.4, 7.7) [0.028]

Notes: KOOS4 AUC was divided by 18 to return values to the 0 to 100 scale. 156 and 159 observations are reported for the surgical management and non-surgical management groups respectively. Reported SD is nominal value calculated from the model based standard error.

Supplementary Table S10: Clinical events reported if participant had contact/assessment with a medical professional

	Surgical Reconstruction (N=156)	Rehabilitation (N=160)
Received surgery, n (%)	113 (72)	65 (41)
Total number of complications	11	12
Total participants with complications	10	11
Complication, n (%)		
Event related instability	1	0
Meniscal pathology (newly acquired)	1*	3
Suspected DVT	1	0
Swelling/haematoma	1	1
Unexplained knee pain	0	1
DVT	1	0
Graft failure	2	1
Infection	1**	1
Meniscal & Posterolateral Corner (PLC) pathology newly acquired	1	0
Patellofemoral related pain	1	2
Superficial skin infection (graft harvest)	1	0
Suspected ligament damage	0	2
Suspected vascular abnormality	0	1

* Medial and lateral meniscal tears (new) prior to undergoing ACL surgery

** Overnight stay for IV flucloxacillin

Supplementary Table S11: Clinical events reported if participant had contact/assessment with a medical professional (as treated):

	Surgery	Rehabilitation (No-Surgery)	Rehabilitation (but underwent subsequent surgery)
Total number of complications	15	1	7
Total participants with complications	14	1	6
Complication, n (%)			
Event related instability	1	0	0
Meniscal pathology (newly acquired)	1	1	2*
Suspected DVT	1	0	0
Swelling/haematoma	2	0	0
Unexplained knee pain	1	0	0
DVT	1	0	0
Graft failure	2	0	1
Infection	1	0	1
Meniscal & Posterolateral Corner (PLC) pathology newly acquired	1*	0	0
Patellofemoral related pain	3	0	0
Superficial skin infection (graft harvest)	1	0	0
Suspected ligament damage	0	0	2
Suspected vascular abnormality	0	0	1

*Event occurred prior to surgery

Supplementary Table S12: Analysis of EQ-5D secondary outcome at 18 months post randomisation

EQ-5D	Surgical Reconstruction	Rehabilitation	Mean difference (95% CI)	P-value
EQ-5D-5L Index, n, mean (SD)	0.77 (0.23)	0.72 (0.24)	0.04 (-0.02, 0.10)	0.22
EQ-VAS, n, mean (SD)	77.7 (16.3)	75.9 (16.2)	-	-

Notes: 115 and 116 observations are reported for the surgical reconstruction and rehabilitation groups respectively EQ-5D-5L Index and 114 and 113 observations respectively for the EQ-VAS

Supplementary Table S13: Analysis of ACL-QOL secondary outcome at 18 months post randomisation

ACL-QOL	Surgical Reconstruction		Rehabilitation		Mean difference (95% CI)	P-value
	n	Mean (SD)	n	Mean (SD)		
Overall score	89	59.7 (24.5)	82	48.2 (26.3)	11.6 (4.4, 18.8)	0.0028

Supplementary Table S14: Analysis of patient satisfaction secondary outcome at 18 months post randomisation

Patient satisfaction	Surgical Reconstruction	Rehabilitation	Difference in proportions (95% CI)
Better than before, n (%)	102 (83)	79 (68)	15 (4, 25)
Same treatment again, n (%)			
Yes	98 (80)	71 (61)	-
No	6 (5)	21 (18)	-
Unsure	19 (15)	24 (21)	-

Supplementary Table S15: Analysis of patient satisfaction secondary outcome for PPP population at 18 months post-randomisation

Patient satisfaction	Surgery (Surgical Reconstruction)	Rehabilitation (Non-Surgical)
Better than before, n (%)	81 (86)	64 (66)
Same treatment again, n (%)		
Yes	83 (88)	59 (61)
No	0 (0)	16 (16)
Unsure	11 (12)	22 (23)

Supplementary Table S16: Analysis of patient satisfaction secondary outcome for PPC population at 18 months post-randomisation

Patient satisfaction	Surgical Reconstruction	Rehabilitation
Better than before, n (%)	81 (87)	49 (68)
Same treatment again, n (%)		
Yes	83 (89)	47 (65)
No	0 (0)	11 (15)
Unsure	10 (11)	14 (19)

Supplementary Table S17: Tegner Activity Score secondary outcome at 18 months post randomisation

	Surgical Reconstruction	Rehabilitation	P-value
Tegner Activity Score, median (IQR)	5 (3, 6)	4 (3, 5)	0.0065
Return to pre-injury activity level, n (%)	27 (28)	21 (24)	-
Did not reach expected return level, n (%)	65 (68)	63 (73)	-

Notes: 95 and 86 observations are reported for the surgical management and non-surgical management groups respectively.

Supplementary Table S18: Non-Surgical Management (Rehabilitation) minimum standard as outlined in protocol and example of rehabilitation protocol from a participating site

Non-Surgical Management (Rehabilitation):

Patients randomised to rehabilitation will be referred to their nearest physiotherapy department and undergo non-surgical management (Rehabilitation) delivered (or closely overviewed) by a senior physiotherapist with experience of ACL injury regimens. The routine rehabilitation protocol used at the participating site will be followed.

As part of the site selection process, documentary evidence of the use of or willingness to adopt a rehabilitation protocol that reflects the guidelines of the mandatory aims/goals set for the study rehabilitation intervention (see below) will be required. Part of the requirement will be for the site to be in a position to provide a minimum of six rehabilitation sessions delivered over at least a three-month period.

The rehabilitation protocol will include the following components:

- Evidence of interventions aimed at achieving the mandatory aims/goals:

1. Control of pain and swelling

2. Regaining range of movement

3. Improving neuromuscular control

4. Regaining muscle strength

5. Achieving normal gait pattern

6. Returning to function/activity/sport.

- Clearly identified progression milestones.
- Return to sport criteria.

Rehabilitation protocols commonly used in clinical practice consist of a progressive programme, designed to rebuild muscle strength, re-establish joint mobility and neuromuscular control, and enable patients to decrease the risk of re-injury and return to previous levels of activity.

As there is little consensus in the literature over the most effective rehabilitation protocol, variation in the specific exercises carried out and use of adjuncts (such as cryotherapy) to reach these aims is permitted. Examples of exercises used to reach the aims will be documented in a physiotherapy case report form (PCRF). Flexibility is permitted to adapt treatment to individual needs with no timelines specified for progression. Evidence of individual progression however will be documented in the PCRF. A physiotherapy case report form (PCRF) will be used to facilitate recording of the rehabilitation interventions to monitor for fidelity to these guidelines.

Procedure:	**Anterior Cruciate Ligament Reconstruction (with hamstrings graft)** **<u>NON – ACCELERATED PROGRAMME</u>** This protocol is a general guide to rehabilitation. Always check the post-op notes for any variation.
0-2 weeks:	• Toe-touch weight bearing with elbow crutches • Brace 0-90 degrees • Full extension (Avoid hyperextension for 12 weeks) • Passive and active flexion exercises • Ice and modalities to reduce pain and inflammation • Circulation exercises • Patella mobilisations • Static quads exercises (But not beyond 0 degrees) • Core stability and glutes exercises **NB. ACL Graft is at its weakest between 6 - 12 weeks** **NO open chain quads (Between 0-50 degrees) for 18 weeks** **NO hyperextension or flexion beyond 120 degrees for 12 weeks** **NO cyclical loading for 12 weeks** **(e.g. cycling/wall slides/sit to stand/step ups/cross trainer)** **NO manual or unpredictable work for 12 weeks**
2 - 6 weeks:	• Continue above • Continue Brace 0-90 degrees (From 3 weeks can remove brace with physio to do active-assisted flexion to 110 degrees) • Normalise Gait – wean off crutches as pain and quadriceps allow • Scar massage to prevent adherence • Full patella mobility • Hamstring management – soft tissue techniques/gentle stretching • Commence 'Wall push' Isometric quads and hams - in supine with legs at 90 degrees and feet against wall (gravity eliminates ant tibial translation from quads) • Commence proprioceptive control – single leg stand (From 3 weeks)
6 - 12 weeks:	• Wean out of brace • Gradual increase intensity glut/ core work (Restore control and balance) • Active range of movement to 120 degrees • Gentle hamstrings strengthening exercises (prone knee curls) • Continue swelling control, scar management and patella mobility • NO through range closed chain quads (e.g. No dips/squats/step downs) • NO gym work • NO treadmill or cyclical loading • NO swimming

12–18 weeks:	• Full range of movement • Commence aerobic work including cross trainer and cyclical loading • Commence closed chain quadriceps strengthening (isometric/eccentric) e.g. squats, sit to stand, single leg dips • Wall slides 60 to 90 degrees flexion (isotonic) • Swimming – crawl/backstroke only (NO breast stroke) • No jogging • No impact work • Progress proprioceptive and rotational control
18-24 weeks:	• Commence impact work/running ONLY if full extension and good eccentric quads control - hamstrings and quads regained 80 % compared to unaffected limb. (Start with trampette, progress to straight line/ flat jogging) NO plyometrics • May begin open chain quads with no resistance • Consider Isokinetic Cybex Assessment if appropriate
6-9 months: months	• Resisted open chain quads • Introduce plyometrics • Progressive introduction of dynamic activity, with emphasis on alignment at both push off and land. - Flat and uphill jogging, progress to downhill - Change of direction - cutting/multidirectional/pivoting/backwards - Jumping/hopping (start on the trampette) - Stop/start acceleration and deceleration - Lateral hops/ z hops/ landing/skipping • Prior to return to sports specific training, patient must achieve satisfactory single limb dynamic control. • Consider Isokinetic Cybex Assessment if returning to sport
9 months onwards:	• Return to non-competitive training initially, aiming for full competitive sport at 1 year.
Functional Goals:	Driving – 6 weeks (dependant on range and quads) Swimming – 12 weeks (once wound healed) NO BREAST STROKE Cycling – 12 weeks (Normal pedals only) Golf – If right-handed, right ACL – 6 months, left ACL – 9 months Jogging - 18-24 weeks dependant on range and quads strength Competitive sport – 1 year (Return non-contact training initially)