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Internal brace augmentation reconstruction VS standard anterior cruciate ligament reconstruction:A randomized controlled clinical trial study protocol.

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4 1 **Internal brace augmentation reconstruction VS**
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6 2 **standard anterior cruciate ligament reconstruction :**
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8 3 **A randomized controlled clinical trial study protocol.**
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Abstract:

Introduction: Anterior cruciate ligament (ACL) rupture is one of the most common knee injuries in sports, and the gold standard for treating ACL rupture is tendon graft reconstruction. Recently, internal brace technology has been gradually applied to ligament repair, but there is still a lack of relevant in vivo clinical evidence for the use of internal brace technology in ACL reconstruction. We conducted a randomized controlled trial to investigate the clinical efficacy of internal brace technology in ACL reconstruction.

Methods and analysis: This is a randomized, parallel controlled trial of patients with ACL rupture who underwent inpatient surgery at the Department of Orthopedics, Xiangya Hospital, Central South University. All study subjects were assigned to the test and control groups according to the random number table method. The test group underwent ACL reconstruction using the internal brace technique, and the control group underwent standard ACL reconstruction, with uniform postoperative rehabilitation in both groups. Patient-reported outcomes were preoperative baseline and postoperative recovery at 1, 3, 6, 12, and 24 months. The primary outcome was International Knee Documentation Committee (IKDC) function from baseline (ACL rupture) to 6 months postoperatively. Secondary outcomes included (I) other patient outcome reporting metrics, the Lysholm knee score (LKS), the Knee Injury and Osteoarthritis Outcome Score (KOOS), and the Visual Analog Scale (VAS), (II) the use of the Kneelax3 knee stabilizer to assess knee stability, (III) the occurrence of adverse events, such as graft refraction or symptomatic instability, postoperative infection, and contralateral injury, and (IV) magnetic resonance images at 12 and 24 months after ACL reconstruction.

Ethics and dissemination: This trial was approved by the Medical Ethics Committee of Xiangya Hospital of Central South University on October 26, 2021. Data will be published in peer-reviewed journals and presented at national and international conferences.

Trial registration number: ChiCTR2200057526.

Strengths and limitations of this study:

- Internal Brace augmentation reconstruction is the standard ACL reconstruction with Internal Brace technology.
- Randomization divided the included patients into Internal Brace augmentation reconstruction group and standard ACL reconstruction group.
- Prospective follow-up and data collection to comparatively analyze the need for enhanced reconstruction of Internal Brace.
- The study has a standard and detailed rehabilitation training program.
- This trial was conducted in a single center and the data lacked generalizability.

Key words:

anterior cruciate ligament (ACL), anterior cruciate ligament reconstruction, internal brace, study protocol.

95

96 Introduction

97 Anterior cruciate ligament (ACL) rupture is one of the most common ligament injuries
98 in the knee, mainly in young people who participate in sports. If not actively treated
99 after injury, joint instability and other phenomena often occur, which will reduce the
100 quality of life and increase the risk of osteoarthritis⁽¹⁻³⁾. Over the past few decades, the
101 incidence of ACL ruptures has been estimated at approximately 30 to 52 cases per
102 100,000 person-years(4). ACL injuries occur in more than 175,000 people in the United
103 States each year, and approximately 100,000 of those people undergo surgery(5-7). A
104 41-year-old miner successfully performed the world's first ACL repair surgery, and the
105 function of the knee joint was very good after surgery(8). With the continuous
106 development of surgical techniques, the current mainstream surgical method is to
107 perform ACL reconstruction under arthroscopy(9). In recent years, a Japanese study
108 found that for rugby players under the age of 20 after ACL reconstruction, the
109 redisruption rate of ACL reconstruction grafts after returning to the field was 23%(10).
110 At the same time, other studies have also shown that the revision rate of ACL
111 reconstruction with allogeneic tendon in adolescents can reach 35%(11); however, the
112 effect after revision is not as good as that of primary ACL reconstruction(12).

113
114 Internal brace technology was promoted in 2010, which uses braided ultrahigh
115 molecular weight polyethylene (UHMWPE) polyester suture tape and knotless bone
116 anchors to reinforce ligament strength, also known as an auxiliary stabilizing structure
117 for recovery of motion after ligament repair, which helps prevent secondary damage,
118 (13)such as anterior and posterior cruciate ligament, medial and lateral collateral
119 ligament repair of the knee(13-15), and ankle and elbow ligament strengthening
120 repair(16, 17). Enhanced collateral ligament repair and reconstruction with internal
121 brace improves limb biomechanics, including greater stiffness and maximum load,
122 while facilitating early rehabilitation in the motor and biomechanical environment (12,
123 14). Reinforced ligament repair offers unique advantages over traditional
124 reconstruction techniques, including smaller bores and implants, no risk of disease
125 transmission from allografts, and no risk of tunnel convergence during the procedure
126 (14, 18, 19). Therefore, ACL reinforcement is an alternative method for supporting
127 ACL grafts in a synergistic load-sharing manner with primary tension on the graft and
128 high-strength suture tape.

129
130 In the case of ACL reconstruction, the internal brace ligament augmentation technique
131 helps prevent a variety of failure scenarios, including creep and irreversible stretching,
132 traumatic tears, and slippage of the tendon-bone interface(20, 21). In addition, these
133 failures can be avoided when the graft is small or vulnerable(20, 21). In 2018, in an in
134 vitro trial, Dr. Pat Smith found that ACL reconstruction combined with independent
135 suture tape significantly reduced graft elongation and allowed the grafted ligaments to
136 accept higher ultimate disruption loads, thereby reducing the risk of rerupture of the
137 graft(20). Preliminary short-term studies have shown that the use of the internal brace
138 technique can significantly improve functional recovery after ACL reconstruction and
139 improve patient quality of life, but there are only a few medical institutions that use
140 ACL reconstruction combined with the internal brace technique, and there is a lack of
141 relevant in vivo clinical evidence.

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143 This study will fill this gap by exploring whether internal brace technology can improve

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3 144 the outcome of patients with ligament injuries and provide a new option for patients
4 145 with ACL injuries.

5 146 **Methods and analysis**

6 147 **Study setting**

7 148 This was a randomized parallel-controlled trial of patients with ACL rupture who were
8 149 hospitalized in the Department of Orthopedics at Xiangya Hospital of Central South
9 150 University from 03/2022 to 03/2023. The Medical Ethics Committee of Xiangya
10 151 Hospital of Central South University approved the ethical application related to this
11 152 study and has filed it (ethical approval number: 202110478). All subjects signed the
12 153 informed consent form before the operations.
13 154

14 155 **Eligibility criteria**

15 156 The inclusion criteria are as follows: (1) age of 16-45 years; (2) unilateral knee MRI
16 157 showing unilateral knee ACL fracture; (3) combined meniscal injury that does not
17 158 interfere with the standard postoperative rehabilitation program after intraoperative
18 159 management; (4) combined grade III or lower cartilage injury that does not interfere
19 160 with the standard postoperative rehabilitation program; (5) satisfaction of 24 months of
20 161 follow-up; (6) no previous injury to the healthy knee; (7) informed consent of the
21 162 subject and signing of relevant documents.

22 163 The inclusion criteria are as follows: (1) age of <16 years or >45 years; (2) previous
23 164 ACL reconstruction or bilateral ACL injury; (3) MRI revealed posterior cruciate
24 165 ligament (PCL), medial collateral ligament (MCL), or lateral collateral ligament (LCL)
25 166 injury; (4) grade IV cartilage injury or unstable longitudinal meniscus tear requiring
26 167 repair that interferes with standard rehabilitation protocols after surgical management;
27 168 (5) patients who cannot meet 24 follow-up visits; (6) patients with severe underlying
28 169 medical conditions that make surgery inadvisable, or patients with mental illness,
29 170 pregnancy during planned trials, or other conditions that are not conducive to late
30 171 follow-up.
31 172

32 173 **Participant selection:**

33 174 Patients diagnosed with ACL rupture by clinicians through physical examination and
34 175 MRI imaging evaluation were assigned to the trial and control groups according to the
35 176 time of admission according to the random number table method after final
36 177 confirmation of ACL rupture under arthroscopy. The trial group was reconstructed
37 178 using ACL reconstruction with the internal brace technique, and the control group was
38 179 reconstructed using ACL reconstruction without the internal brace technique.
39 180 Preoperative assessment of patients was performed before surgery, and a uniform
40 181 rehabilitation program was performed after surgery. The protocol (version 1.0, March,
41 182 2022) inclusion start date was March 2022, with an expected cutoff date of March 2023.
42 183 The follow-up period is 2 years, with the last follow-up expected in March 2025 (the
43 184 exact end date is based on the inclusion of the last subject), and the specific technical
44 185 route is shown in **Fig. 1**.
45 186

46 187 **Study sample**

47 188 IKDC score consists of three aspects: 1) symptoms, including pain, stiffness, swelling,
48 189 interlocking/jamming, and playing with a tender leg; 2) motion and daily activities; and
49 190 3) current knee function and knee function before the knee injury (not included in the
50 191 total score), which is the main outcome indicator of this study, based on which the
51 192 sample size required for this trial was estimated. The minimum clinically important
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3 193 difference (MCID) of the IKDC scale was reported to be between 8.8 and 15.6⁽²²⁻²⁴⁾,
4 194 we set δ to 10, and the overall sample standard deviation was set to 13 based on the
5 195 relevant literature⁽²²⁻²⁴⁾. To satisfy the test efficacy ($1-\beta$) of 0.8 and the test level α of
6 196 0.05, the sample size calculated for each group was 27 according to the following
7 197 formula, and considering a 20% lost visit rate, 32 patients were included in each group
8 198 with a total of 64 patients included.
9 199

200 **Randomization and Concealed Grouping**

201 All eligible subjects were included after screening by inclusion and exclusion criteria,
202 and the subjects enrolled were randomly assigned to the ACL reconstruction with
203 internal brace technique group (combined group, n=32) and the standard ACL
204 reconstruction group (simple group, n=32) using the random number table method. The
205 occurrence of adverse events was recorded throughout the follow-up. All data were
206 collected by 2 physicians who were unaware of the grouping. During postoperative
207 rehabilitation, all subjects were given a uniform standard rehabilitation program by a
208 professionally trained and relevant rehabilitation physician or clinician, and the
209 rehabilitation therapist was not aware of the patient's intraoperative condition.
210

211 **Interventions and surgical techniques**

212 In all cases, all inside ACL reconstruction was performed using autologous
213 semitendinosus tendons with the aid of knee arthroscopy. Semitendinosus tendons were
214 braided with sutures (0 FiberWire Suture, Arthrex) to form four strands of ACL grafts
215 (all between 7.5 and 10 mm in diameter, supplemented with semimembranous tendons
216 less than 7.5 mm in diameter). In the ACLR group, the braided graft femoral end and
217 tibial segment were suspended and fixed with a TightRope (ACL TightRope RT
218 Implant, Arthrex), and in the ACLR with internal brace group, a separate wire tape (2
219 mm FiberTape, Arthrex) was added to the ACLR group, and the suture was fixed with
220 a knotless bone anchor (4.75-mm PEEK SwiveLock, Arthrex) distally and a TightRope
221 suspension proximally as in the graft. **Fig. 2.**
222

223 The procedure was as follows: the patient was anesthetized, a tourniquet was applied
224 to the affected limb, routine surgical disinfection of the knee was performed, a sterile
225 surgical sheet was placed, the semitendinosus tendon was palpated, a straight incision
226 was made medial to the tibial tuberosity, the semitendinosus tendon was removed with
227 a tendon extractor, 10 ml of ropivacaine was injected at the tendon extraction site, and
228 then, the removed semitendinosus tendon was braided into 4 strands using the
229 GraftLink (Arthrex) technique⁽²⁵⁾. A conventional knee arthroscopic approach was
230 performed on the anteromedial and anterolateral sides of the affected knee to explore
231 the injured structures and remove the remaining portion of the ACL. The knee was
232 flexed to the extreme, and the femoral tract was created at the footprint of the ACL stop
233 at the lateral femoral condyle and the tibial tract at the footprint of the ACL start. The
234 graft and two TightRope titanium plates were pulled into the knee cavity and pulled out
235 through the femoral and tibial tracts, respectively. The tabs were flipped, the tab rings
236 were tightened, and the titanium plates were fixed. In the ACLR with internal brace
237 group, the femoral end of the FiberTape wire band was fixed with a TightRope ring,
238 the wire band was tensioned in the extended position, and the tibial end was fixed
239 independently with a knotless bone anchor (4.75-mm PEEK SwiveLock, Arthrex).
240

241 All patients received a uniform training and rehabilitation program after surgery, and
242

242 the entire rehabilitation process was divided into 7 phases. The first 3 phases focused
 243 on controlling swelling and restoring range of motion, which usually required 4 weeks.
 244 Detailed rehabilitation plan can be found in **Table 1**. Phases 4-5 focused on restoration
 245 of quadriceps muscle strength control, balance and core strength restoration training,
 246 and phases 6-7 were gradually resumption of various sports activities, from daily
 247 activities to professional activities or contact sports. Detailed rehabilitation plan can be
 248 found in **Table 2** and **Table 3**.

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Table 1. phases 1-3 of the post-ACL reconstruction rehabilitation program

Phase	Movement Exercises	Gait Exercises	Manipulative Massage	Rehabilitation Goals	Precautions
Phase 1 (within 1 week)	(1) Bed heel against the bed for flexion and extension sliding; supine position, the affected leg bends the hip, flexes the knee and places the heel on the wall for flexion and extension sliding; sitting position, legs on the floor, the healthy leg is placed in front of the affected leg and assists the affected leg in flexing the knee. (2) Ankle pump exercises (the affected leg is elevated, and the foot performs upward hooking and downward stepping movements, as well as rotational movements). (3) Anterior thigh muscle tensing exercises with the knee in the straight position (can be combined with neuromuscular electrical stimulation or biofeedback exercises). (4) Hip muscle group training. (5) Pillow clamping of the legs for medial thigh muscle group strength training. (6) The brace is locked in the 0° position, and the affected leg is lifted in the supine, prone and prone positions for muscle strength training. (7) Passive knee extension exercises: prone position with the affected knee extended out of the bed for suspension or supine position with the affected leg in a slightly elevated heel position and the knee joint suspended. (8) In the above weight-bearing exercise position, weight transfer training (front-to-back and left-to-right) can be performed. (9) Continuous passive movement apparatus training with increased knee flexion by 5° to 10°/day.	(1) Flat and step gait training with the support of a knee protection brace and double crutches. (2) Cold compresses after training to reduce edema.	(1) Push the patella in all directions. (2) Manipulation of the posterior thigh muscles of the affected limb or sitting and standing to pull the muscles to relieve their spasm.	Active mobility of the knee joint reaches 0° to 90°. (1) The anterolateral thigh muscles can be tightened better. (2) The affected limb can be fully weight bearing with the help of braces and crutches. (3) Edema control is good. (4) Good wound healing.	(1) Brace locked in 0° position, crutches, and weight-bearing exercises within tolerable range. (2) Wear the brace at night and lock it in the 0° position while sleeping with the affected leg elevated.
	Phase 2 (1-2 weeks)	(1) Fixed cycling exercises (from small to full range of pedal rotation). (2) Tightening exercises and 90° muscle strength exercises for the anterior thigh muscles in the straight position.	(1) The healthy leg stands outside the treadmill with weight, and the	(1) Manipulation to push the patella treatment.	The active mobility of the knee joint reaches 0° to 120°. (1) Straight leg elevation; anterior

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4		(3) Standing balance training on the	affected leg	(2)	thigh muscles can
5		affected leg with a single leg wearing a	simulates	Manipulation	be tightened with
6		support.	walking on the	n of the	force.
7		(4) Balance training on a balance board	treadmill.	posterior	(2) With crutches,
8		with forward and backward weight	(2) The affected	thigh muscle	the patient can
9		transfer.	leg crosses the	group for	walk normally with
10		(5) Continuous passive activity equipment	obstacle training	relaxation	a nonlocking brace.
11		training.	and simulates	and	
12		(6) Start small partial weight-bearing squat	walking.	stretching	
13		exercises (within 30° of knee flexion).		exercises.	
14		(7) Passive straightening exercises with the			
15		heel slightly elevated and the knee hanging			
16		in the air.			
17		(8) Straight leg raises training (all			
18		directions).			
19		(9) Terminal angle knee extension training			
20		in the standing position using an elastic			
21		band.			
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30		(1) Fixed bicycle training gradually			
31		increases the resistance to improve			
32		exercise endurance.			
33		(2) Tightening exercises for the anterior		(1)	
34		thigh muscle group in the straight position		Manipulation	The knee joint
35		and muscle strength exercises in the range		n to push the	moves to an active
36		of 60° to 90° until the muscle strength of		patella	full angle, in line
37		both legs is equal.		treatment.	with the healthy
38		(3) 0° to 60° squat training, gradually	Exercise with	(2)	side leg.
39		increasing the resistance strength (for	rope tied around	Manipulation	(1) Normal gait can
40		patients with meniscal repair, squat to the	the waist or on a	n of the	be achieved
41		target angle on the healthy leg before	treadmill for	surgical	without any
42		shifting the weight to the middle of the two	forward and	scar.	walking aid.
43		legs).	backward gait	(3)	(2) Self-care of
44		(4) Stand with both legs on a balance board	training.	Manipulative	daily life (may
45		for balance training in multiple directions.		e passive	have some
46		(5) Single-leg standing balance training on		knee flexion	difficulty in
47		the affected leg (with eyes closed and open		or extension	walking up and
48		and on a support surface with different		angle	down steps).
49		degrees of softness).		exercises.	
50		(6) Straight leg raise training in the			
51		standing position, which can increase the			
52		resistance appropriately.			
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Table2: Phases 4-5 of the post-ACL reconstruction rehabilitation program

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Phase	Movement Exercises	Gait Exercises	Manipulative Massage	Rehabilitation Goals	Precautions
Phase 4 (4-8 weeks)	(1) Fixed cycling training: gradually increasing the resistance.				
	(2) Squat training: Double leg transition to a single leg (0° to 60°), gradually increasing resistance.			(1) Center of gravity in the middle, squatting bilaterally to 60° (no more than 60°).	
	(3) Lunge training (0° to 60°).			(2) Knee in good condition (slight pain and effusion, no instability).	(1) Do not participate in sports with high impact on the joints, such as running, jumping.
	(4) Step training: centripetal and centrifugal contraction of the anterior thigh muscles (knee does not exceed 60°).			(3) The circumference at the upper edge of the patella is 10 cm within a 1 to 2 cm difference between the legs.	(2) Do not participate in sports with high lateral stress on the joints.
	(5) Tiptoe training: Double leg transition to single leg.			(4) The affected limb can maintain balance for > 30 seconds while standing on one leg with little body sway.	(3) Try not to squat deeply (limit to 0° to 60°).
	(6) Swing exercise: the affected leg stands on one leg, and the healthy leg is strapped with an elastic band and swings, transitioning from front-to-back swing to lateral swing and then to rotation or random direction movement.	Go around obstacles at normal walking speeds on different surfaces.		Manual method to loosen surgical scars.	
	(7) Rotational stability training: static lunge stance, lateral pull pulley exercise.				
	(8) Exercise with rope tied around the waist to provide resistance; walking exercises in the forward and backward, left and right directions.				
	(9) Walking exercises on the treadmill in 4 directions.				
	(10) Balance board training: a variety of support surfaces, double-legged standing.				
	(11) Single-leg stand for ball tossing exercises.				
	(12) Core training: supine or prone position for bridge exercise, standing pull pulley.				
Phase 5 (8-12 weeks)	(1) Squat training: transition from double to single leg (0° to 60°), gradually increasing resistance.			(1) The thigh circumference of both legs is close to the same (within 1 cm of each other).	
	(2) Lunge training (0° to 60°).			(2) The affected limb squats down to 60° on one leg.	Patellar tendonitis may occur.
	(3) Tiptoe training: double-leg transition to single-leg.			(3) The affected limb can stand on one leg to maintain balance for 60 seconds.	
	(4) Increasing the strength of the posterior lateral muscle group with plyometric training. Core muscle strength training.			(4) Little, if any, edema with activity.	
	① Combined strength training with balance training (throwing and catching balls on balance board, small squat on balance board, etc.)	—	—		
	② Advanced balance function training (affected leg standing on one leg, hand or opposite foot to touch objects on the ground or lateral pulling elastic band)				
	③ Swimming training, in addition to breaststroke. Additionally, care should be taken not to stir the leg at a deep squatting angle or to use a splint when swimming.				
	④ Cycling training every other day.				

256 **Table 3: Phases 6-7 of the post-ACL reconstruction rehabilitation program**

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Phase	Movement Exercises	Gait Exercises	Manipulative Massage	Rehabilitation Goals	Precautions
Phase 6 (12-16 weeks)	(1) Jogging movement: multiple directions for running. (2) Increasing the speed of all sports. (3) Skateboard training, slow walking in the water and other forms of exercise can be carried out.	—	—	(1) Squat down to 60° on one leg with the affected limb and repeat 20 times. (2) The affected leg can stand on one leg to maintain balance for at least 60 seconds. (3) Vertical or horizontal jump with both legs with good landing position. (4) Single-leg jump: 80% of the ability of the healthy leg is achieved.	Avoid wrong movements or posture. (1) Landing with the knee joint too straight. (2) The knee joint is turned outward or inward when landing. (3) When landing or bouncing, the healthy leg always takes the lead, and the affected leg does not.
	(1) Jogging movement: multiple directions for running. (2) Increasing the speed of all sports. (3) Skateboard training, slow walking in the water and other forms of exercise can be carried out.	—	—	(1) Squat down to 60° on one leg with the affected limb and repeat 20 times. (2) The affected leg can stand on one leg to maintain balance for at least 60 seconds. (3) Vertical or horizontal jump with both legs with good landing position. (4) Single-leg jump: 80% of the ability of the healthy leg is achieved.	Avoid wrong movements or posture. (1) Landing with the knee joint too straight. (2) The knee joint is turned outward or inward when landing. (3) When landing or bouncing, the healthy leg always takes the lead, and the affected leg does not.

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260

261 **Baseline indicators and observations**

262 Baseline and preoperative patient characteristics included the subject's sex, age,
263 affected limb (left or right), cause of injury (playing basketball, other sports such as
264 soccer), smoking status (yes or no), time from injury to surgery (fresh injury or old
265 rupture), whether the injury was accompanied by cartilage and meniscal damage, time
266 of surgery, and degree of ACL fracture (partial or total).

267

268 **Study endpoints**

269 **Primary outcome/endpoint:** The IKDC scores changes in knee function from
270 preoperative to 6 months postoperative. The IKDC is a commonly used tool to evaluate
271 outcomes after various knee surgeries, including ACL reconstruction(26). The IKDC
272 knee score consists of a knee assessment (10 entries) and a knee ligament checklist (8

273 entries), covering joint pain, motor level and daily activity ability, with a total score of
274 0 to 100. The IKDC can address knee symptoms, function and physical activity. The
275 IKDC assesses symptoms, function and physical activity of the knee. Patients were
276 evaluated with the questionnaire preoperatively and at follow-up visits at 1, 3, 6, 12,
277 and 24 months postoperatively.

278 **Secondary outcomes/endpoints:** LKS, KOOS (including knee symptoms, pain,
279 activities of daily living, sports and recreational activities, and quality of life), VAS,
280 Lachman test, MRI imaging data, and assessment of knee stability using the Kneelax3
281 knee stability meter.

282 (1) Kneelax3 (MONITORED REHAB SYSTEMS B.V. Model: KNEELAX3, The
283 Netherlands): preoperatively and 1, 3, 6, 12 and 24 months postoperatively; the
284 Kneelax3 arthrometer was used for the assessment of knee stability.

285 (2) Lysholm knee score: This scoring system consists of 8 questions on a scale of 0-
286 100, with higher scores representing better functional status of the patient. The main
287 tendency is toward activities of daily living, and patients were assessed by
288 questionnaires before surgery and at 1-, 3-, 6-, 12-, and 24-month postoperative follow-
289 up visits(27).

290 (3) KOOS score: The KOOS consists of 5 subscales: pain, other knee symptoms,
291 activities of daily living (ADL), function in sport and recreation (Sport/Rec), and knee-
292 related quality of life (QOL)(28). Patients were given one week to consider before
293 answering the questions, and each question had five alternative boxes with scores
294 ranging from 0 to 4. Standard scores were calculated for each subscale (100 for no
295 symptoms and 0 for extreme symptoms), and patients were assessed with
296 questionnaires before surgery and at follow-up visits at 1, 3, 6, 12, and 24 months after
297 surgery.

298 (4) VAS score: This is the visual analog pain scoring method, which is more sensitive
299 and comparable. In this trial, a 100-mm VAS pain score (including resting state score,
300 30-min postwalk score and overall pain level in the past month) was used(29). This
301 protocol only assesses pain at rest, with 0 representing no pain and 100 representing the
302 most severe pain. Patients were evaluated with questionnaires at preoperative and
303 postoperative follow-up visits at 1, 3, 6, 12, and 24 months.

304 (5) Lachman test: This is a test used to assess ACL function with the patient in the
305 supine or prone position with the knee flexed at approximately a 30° angle(30). The
306 examiner uses one hand to immobilize the thigh, while the other hand attempts to move
307 the tibia forward. Positive results suggest that patients with ACL injuries be tested
308 preoperatively and at follow-up visits at 1, 3, 6, 12, and 24 months postoperatively.

309 (6) MRI assessment: MRI was performed at 12 and 24 months postoperatively to assess
310 the patient's reconstructed ACL.

311

312 **Patient termination and withdrawal criteria**

313 Patients may withdraw from this trial at any time. Patients may withdraw from the study
314 for the following reasons.

315 **(1) Surgical failure:** 1) occurrence of infection, 2) no secondary rupture of the
316 reconstructed ligament (rupture of the ligament, rupture of the internal brace
317 augmentation line and both in the trial group, rupture of the reconstructed ligament in
318 the control group), 3) knee instability: patient self-reported knee instability, or Lachman
319 test (+) or Kneelax3 knee arthrometer test revealed a 3-mm difference in comparison
320 with the healthy side.

321 **(2) Patient withdrawal from the trial:** All subjects had the right to withdraw from the

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3 322 trial at any time during the study. A subject was withdrawn from the trial if any of the
4 323 following occurred during the trial: 1) withdrawal of informed consent by the subject;
5 324 2) a person who, in the opinion of the investigator, is no longer suitable for continuation
6 325 of the clinical trial; 3) a woman who becomes pregnant during the clinical trial; 4) death
7 326 of the subject; or 5) the subject is lost to follow-up.

327 **(3) Trial termination:**

328 1) The clinical trial institution and the investigator find that the risks to patients of
329 continuing the clinical trial exceed the possible benefits; 2) the ethics committee finds
330 that the rights of the subjects cannot be protected; 3) the sponsor requests termination
331 of the trial for various reasons; and 4) the national administrative authority requests
332 termination.

333 The time and reason for withdrawal from the trial were recorded in detail on the case
334 report form; data were not collected for subjects who also withdrew from the trial or
335 after the subject was deemed surgical failure, but subjects who withdrew from the trial
336 due to adverse events had to be followed up until the adverse events stabilized or
337 resolved or until the investigator deemed that further follow-up was no longer necessary.
338

339 **Data management**

340 The trial used an electronic data collection (EDC) system for data management. The
341 investigator or investigator-authorized research staff completed the electronic Case
342 Report Form (eCRF) through the EDC system in an accurate, timely, complete and
343 standardized manner based on the original information from the subjects. Questionnaire
344 checking, data cleaning and summarization were performed in a timely manner after
345 each follow-up visit. The follow-up survey is proposed to adopt the electronic
346 questionnaire system of questionnaire star and on-site questionnaire survey, and the
347 results of the on-site survey will be saved in time and organized in the database later.
348 The data are entered by the investigator or the investigator's authorized researcher into
349 the EDC according to their respective accounts. The data administrator verifies the
350 reliability, completeness, and accuracy of the data in the EDC. If any questionable data
351 are found, a challenge can be issued in the system, and the investigator or the
352 investigator's delegated researcher verifies, corrects, or answers the query. When all
353 data have been entered into the database and all queries have been resolved, the
354 database will be locked by the data administrator. If there is a problem found after the
355 database is locked and there is a need to correct it, the process of unlocking and
356 relocking the data should be followed. After the database is locked, the data manager
357 submits the data to the statistical analyst for statistical analysis as scheduled.
358

359 **Statistical analysis**

360 **(1) Statistical design:** This trial was a randomized controlled clinical trial.

361 **(2) Principles of Statistical Analysis:** All statistical analyses were performed in SAS
362 version 9.4 or later, R version 3.3.2 or later, or SPSS24. All statistical tests were
363 performed using two-sided tests, and P values less than or equal to 0.05 were considered
364 statistically significant for the differences tested (unless otherwise specified).

365 1) Summary statistics for continuous variables: including the mean, standard deviation,
366 median, minimum, maximum, lower quartile (Q1), and upper quartile (Q3); summary
367 statistics for categorical variables, including the number of cases and percentage of each
368 category.

369 2) Between-group comparisons of demographic baseline characteristics: Group
370 comparisons for continuous variables will be made using independent samples t test

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3 371 (chi-square, normal distribution) or Wilcoxon rank sum test depending on data
4 372 distribution, and chi-square test or the exact probability method for categorical
5 373 variables (if chi-square test is not applicable).

6 374 **(3) Completion and demographic analyses**

7 375 Baseline analyses were based on the full analysis set (FAS). The enrollment and
8 376 completion status of the trials were summarized, and the reasons for noncompletion are
9 377 described in a detailed table. Subjects' demographic characteristics were described and
10 378 compared to measure the comparability of the two groups. Validity reporting data were
11 379 accepted only if the baseline was balanced between groups; otherwise, validity data
12 380 were subject to correction before reporting.

13 381 **(4) Patient-reported outcome validity evaluation indices**

14 382 The outcome validity evaluation will be based on the FAS and the per-protocol set
15 383 (PPS). The statistical description and inference of the data will be based on the
16 384 characteristics of the data and the selection of applicable descriptive indicators and
17 385 hypothesis testing methods.

18 386 **Primary patient-reported outcome:** comparison of IKDC knee scores at 6 months
19 387 (± 2 weeks) postoperatively in the trial and control groups. We will use a linear
20 388 regression model for analysis to correct for some possible confounding factors, such as
21 389 age, sex, and cause of injury. Preoperative baseline IKDC scores were used as
22 390 predictors when conducting the analysis, and IKDC at 6 months (± 2 weeks) was used
23 391 as an indicator of posttreatment outcomes.

24 392 **Secondary patient-reported outcomes**

25 393 1) Because IKDC scores were measured at multiple different time points during patient
26 394 follow-up, we were able to use a linear mixed model to compare changes over time
27 395 between the trial and control groups.

28 396 2) Anterior tibial translation distance is measured by the Kneelax3 knee stability meter,
29 397 and comparisons of anterior tibial translation distance between the test and control
30 398 groups at the same postoperative time points with the same force will be performed
31 399 using either an independent samples t test (chi-square, normally distributed) or a
32 400 Wilcoxon rank sum test. A linear mixed model will also be used to compare and analyze
33 401 the evolution of these consecutive results over time in both groups.

34 402 3) Here, the comparative analysis of failure rate and infection rate in the control group
35 403 versus the test group during the main 6 months will be performed using the chi-square
36 404 test or the t test.

37 405 4) Linear regression of continuous outcomes from baseline to 24 months, such as the
38 406 Lysholm knee score, KOOS score (including knee symptoms, pain, activities of daily
39 407 living, sports and recreational activities, quality of life), Lachman test, and pain visual
40 408 analog score (VAS) protocols, will be used to compare and analyze the evolution of
41 409 these continuous outcomes over time in the two groups using linear mixed models.

42 410 5) The morphology and signal intensity of the postoperative ACL will be assessed using
43 411 MRI methods, and the different treatments will be compared at different time points
44 412 using chi-square tests.

45 413 **Analysis of safety indicators**

46 414 The safety evaluation was based on the safety set (SS) analysis dataset. The
47 415 internationally accepted MedDRA term set classification was used for adverse event
48 416 coding, and the types of adverse events, frequency, severity, and relationship to internal
49 417 brace enhancement line generation and surgery were summarized by group. A detailed
50 418 list of the various adverse events is provided, with special notation for subjects who
51 419 discontinued the trial because of adverse events and for those who experienced serious

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3 420 adverse events. The proportion of patients who developed complications between
4 421 treatments was compared using a chi-square test.

5 422

6 423 **Patient and public involvement**

7 424 Patients and/or the public were not involved in the design, or conduct, or reporting, or
8 425 dissemination plans of this research.

9 426

10 427 **Discussion**

11 428 This trial was conducted as a prospective randomized controlled trial to investigate the
12 429 clinical efficacy of ACL reconstruction with or without the internal brace technique. In
13 430 this 2-year follow-up study, the subjective, objective, and functional outcomes of
14 431 patients who underwent ACL reconstruction with the application of the internal brace
15 432 technique or ACL reconstruction alone were compared. The hypothesis of this study is
16 433 that ACL reconstruction with the internal brace technique will prove to be more stable
17 434 than ACL reconstruction alone in the early postoperative period, with a lower incidence
18 435 of secondary injury, reduced duration and extent of pain, and an earlier return to
19 436 preinjury activity levels, but there may be no significant difference between the two
20 437 groups regarding patient-reported outcome indicators as recovery time increases.

21 438

22 439 ACL rupture is a very common knee injury in the athletic population and has been
23 440 extensively studied over the years. Studies as early as the late 20th century have shown
24 441 that ACLR is superior to ACL repair(31, 32). The ACL is an important structure for
25 442 maintaining knee stability, preventing anterior tibial displacement and limiting
26 443 intratibial rotation(33), making ACL reconstruction surgery the gold standard of
27 444 treatment for patients recovering motion or performing rotational activities after an
28 445 ACL rupture in the knee(34). The recovery of knee function after surgery depends on
29 446 the ability of the ACL graft to withstand appropriate loads during rehabilitation and
30 447 after return to sports. The tendon graft implanted in the human knee joint survives in
31 448 the intra-articular environment and gradually in the ligaments. The graft is fragile and
32 449 vulnerable to reinjury during the preremodeling phase prior to ligamentization(35), so
33 450 a careful rehabilitation program should be developed to prevent reinjury during the
34 451 rehabilitation period. Several studies have found a higher probability of rerupture or
35 452 secondary revision for athletes and adolescents or for ACL reconstruction using either
36 453 autologous tendons or allogeneic tendons(10, 36). Therefore, a surgical approach that
37 454 increases the structural strength of the graft and protects it during the early stages of
38 455 graft ligamentization is of great importance.

39 456

40 457 The biomechanical properties of the intra-articular reconstructed ligaments were found
41 458 to improve at 8 weeks postoperatively for the FiberTape suture applied in a rabbit model.
42 459 Additionally, during this period, FiberTape did not adversely affect bone tunnel healing
43 460 or cause a long-term increase in indicators of inflammation(12). In a dog model, no
44 461 severe inflammation or immune response, bone erosion, or premature OA development
45 462 was observed at 6 months postoperatively(37). The results of these studies will support
46 463 the biocompatibility and safety of intra-articular suture tape for ACLR enhancement.

47 464

48 465 A study of load sharing after ACL graft enhancement by suture tape reported that load
49 466 sharing began at 200 N and 300 N for 7-mm and 9-mm grafts, respectively. The final
50 467 peak load (400 N) would be shared by 31% (7-mm graft) and 20% (9-mm graft) by the
51 468 suture tape(38). Suture tape ligament augmentation may potentially protect biological

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3 469 grafts from excessive peak loading and elongation. After ACL reconstruction in the
4 470 early recovery phase, suture band augmentation increases ACL graft stiffness by 104%
5 471 and the ultimate breaking load by 57%, which will reduce the graft failure rate in
6 472 clinical situations.

7 473
8 474 A recent systematic review paper by Christopher et al. concluded from biomechanical,
9 475 animal and clinical studies that the application of suture tape augmentation in ACL
10 476 reconstruction increases its biomechanical stability(39). Therefore, in this randomized
11 477 controlled trial, we will conduct a prospective observational comparison as well as a
12 478 long-term follow-up to truly elucidate the clinical efficacy of internal bracing in ACL
13 479 reconstruction.
14 480

17 481 **Abbreviations**

18 482 Anterior cruciate ligament (ACL)
19 483 International Knee Documentation Committee (IKDC)
20 484 the Knee Injury and Osteoarthritis Outcome Score (KOOS)
21 485 Lysholm knee score (LKS)
22 486 Visual Analog Scale (VAS)
23 487 ultrahigh molecular weight polyethylene (UHMWPE)
24 488 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)
25 489 activities of daily living (ADL)
26 490 sport and recreation (Sport/Rec)
27 491 quality of life (QOL)
28 492 medial collateral ligament (MCL)
29 493 minimum clinically important difference (MCID)
30 494 electronic Case Report Form (eCRF)
31 495 safety set (SS)
32 496

37 497 **Ethics and dissemination**

38 498 The trial was approved by the Medical Ethics Committee of Xiangya Hospital of
39 499 Central South University on October 26, 2021 with the ethics number "202110478" and
40 500 prospectively registered in the China Clinical Trials Registry on March 14, 2022 with
41 501 the registration number: ChiCTR2200057526. All subjects signed an informed consent
42 502 form before participating in this trial and we will protect the patients from any invasion
43 503 of their private privacy. All investigators will keep the study results confidential until
44 504 after the data are made public, and no data related to the database will be released by
45 505 the investigators without the approval of the principal investigator. We will publish the
46 506 findings and data in peer-reviewed journals, and present them at national and
47 507 international conferences.
48 508

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53 511 Joint Surgery of Xiangya Hospital of Central South University for their unfailing care
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55 513 us.
56 514

58 515 **Author contributions**

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2
3 516 WF-X and YS-L established the study design, WH-L conceived the design and wrote
4 517 the draft manuscript; D-L, ZJ-C, and LY-P were involved in data acquisition, analysis,
5 518 and interpretation; and WQ-X, HF-J, and X-L designed the rehabilitation protocol. All
6 519 authors read and approved the final manuscript.
7
8 520

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13 525 **Competing interests**

14 526 The authors declare that they have no competing interests regarding the present study.
15 527

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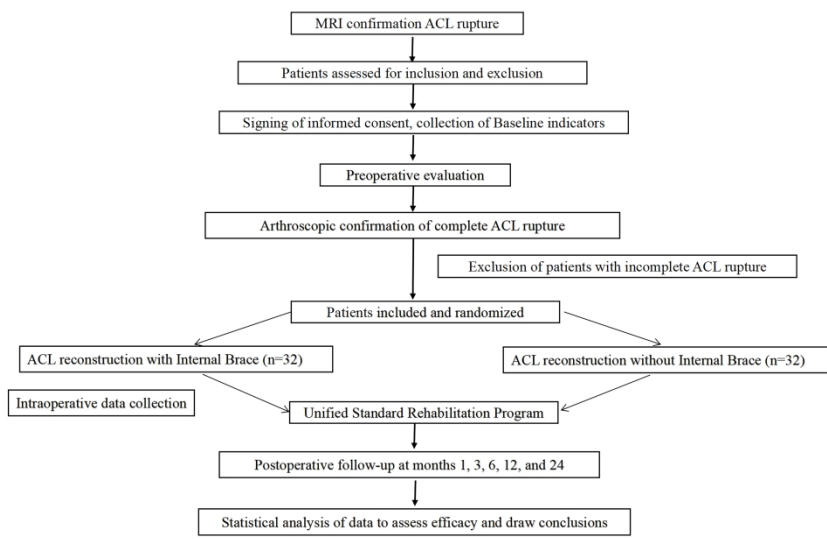
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38 678 **Fig.1** Study Flow Diagram.

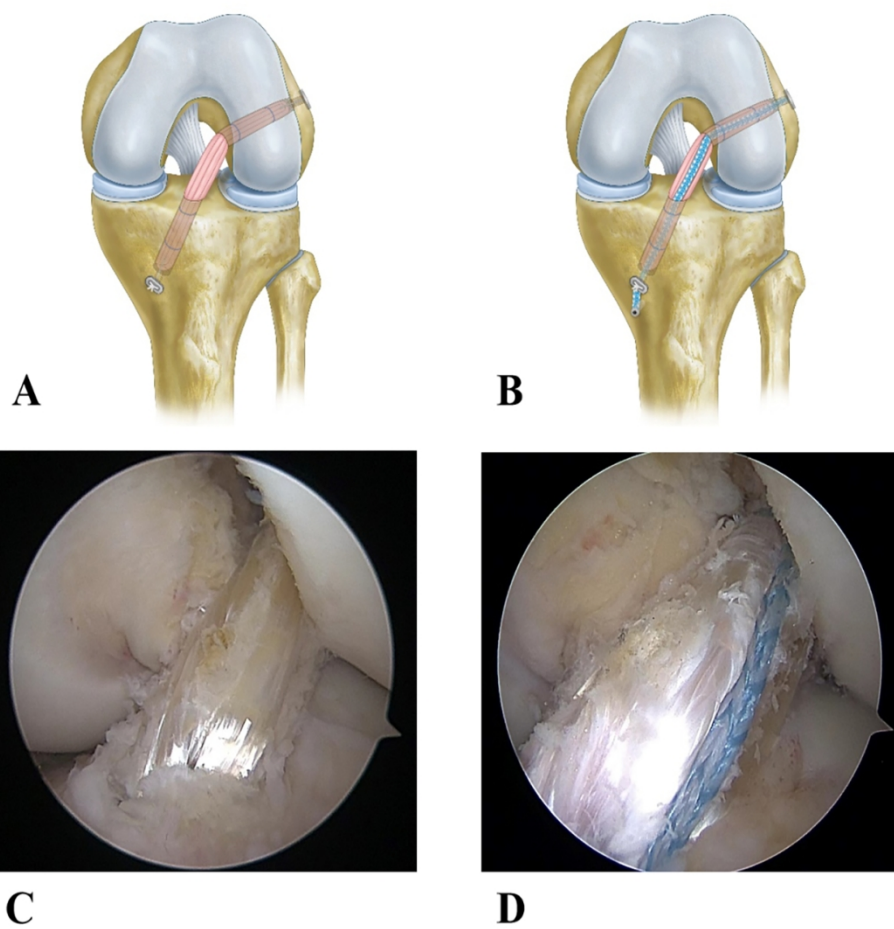
40 679
41 680 **Fig.2** A and B are the models of the control group and test group, respectively. C and
42 681 D are the pictures of the control group and test group after intraoperative arthroscopic
43 682 ACL reconstruction, respectively.

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Study Flow Diagram.

862x485mm (157 x 157 DPI)



A and B are the models of the control group and test group, respectively. C and D are the pictures of the control group and test group after intraoperative arthroscopic ACL reconstruction, respectively.

253x253mm (138 x 138 DPI)

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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			Page
		Reporting Item	Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered,	2

1		name of intended registry	
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4	Trial registration:	#2b All items from the World Health Organization Trial	2
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9	Protocol version	#3 Date and version identifier	4
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17	Roles and	#5a Names, affiliations, and roles of protocol contributors	1
18			
19	responsibilities:		
20			
21	contributorship		
22			
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25	Roles and	#5b Name and contact information for the trial sponsor	11
26			
27	responsibilities:		
28			
29	sponsor contact		
30			
31	information		
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34			
35	Roles and	#5c Role of study sponsor and funders, if any, in study design;	11
36		collection, management, analysis, and interpretation of	
37	responsibilities:	data; writing of the report; and the decision to submit the	
38		report for publication, including whether they will have	
39	sponsor and funder	ultimate authority over any of these activities	
40			
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46			
47	Roles and	#5d Composition, roles, and responsibilities of the	11
48		coordinating centre, steering committee, endpoint	
49	responsibilities:	adjudication committee, data management team, and	
50		other individuals or groups overseeing the trial, if	
51	committees	applicable (see Item 21a for data monitoring committee)	
52			
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1 **Introduction**
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3

4 **Background and** [#6a](#) Description of research question and justification for 3
5
6 rationale
7 undertaking the trial, including summary of relevant
8 studies (published and unpublished) examining benefits
9 and harms for each intervention
10
11
12

14 **Background and** [#6b](#) Explanation for choice of comparators 3
15
16 rationale: choice of
17 comparators
18
19
20

22 **Objectives** [#7](#) Specific objectives or hypotheses 3
23
24

25 **Trial design** [#8](#) Description of trial design including type of trial (eg, 2
26 parallel group, crossover, factorial, single group),
27 allocation ratio, and framework (eg, superiority,
28 equivalence, non-inferiority, exploratory)
29
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35 **Methods:**
36

37 **Participants,**
38
39 **interventions, and**
40
41 **outcomes**
42
43

45 **Study setting** [#9](#) Description of study settings (eg, community clinic, 4
46 academic hospital) and list of countries where data will be
47 collected. Reference to where list of study sites can be
48 obtained
49
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54 **Eligibility criteria** [#10](#) Inclusion and exclusion criteria for participants. If 4
55 applicable, eligibility criteria for study centres and
56
57
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59

1		individuals who will perform the interventions (eg,	
2		surgeons, psychotherapists)	
3			
4			
5			
6	Interventions:	#11a Interventions for each group with sufficient detail to allow	5-6
7			
8	description	replication, including how and when they will be	
9			
10		administered	
11			
12			
13	Interventions:	#11b Criteria for discontinuing or modifying allocated	5-6
14			
15	modifications	interventions for a given trial participant (eg, drug dose	
16		change in response to harms, participant request, or	
17		improving / worsening disease)	
18			
19			
20			
21			
22			
23	Interventions:	#11c Strategies to improve adherence to intervention protocols,	5-6
24			
25	adherence	and any procedures for monitoring adherence (eg, drug	
26		tablet return; laboratory tests)	
27			
28			
29			
30			
31	Interventions:	#11d Relevant concomitant care and interventions that are	5-6
32			
33	concomitant care	permitted or prohibited during the trial	
34			
35			
36	Outcomes	#12 Primary, secondary, and other outcomes, including the	6-7
37			
38		specific measurement variable (eg, systolic blood	
39		pressure), analysis metric (eg, change from baseline, final	
40		value, time to event), method of aggregation (eg, median,	
41		proportion), and time point for each outcome. Explanation	
42		of the clinical relevance of chosen efficacy and harm	
43		outcomes is strongly recommended	
44			
45			
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52			
53	Participant timeline	#13 Time schedule of enrolment, interventions (including any	6-7
54			
55		run-ins and washouts), assessments, and visits for	
56			
57		participants. A schematic diagram is highly recommended	
58			
59			
60			

(see Figure)

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3			
4	Sample size	#14	Estimated number of participants needed to achieve 4
5			
6			study objectives and how it was determined, including
7			
8			clinical and statistical assumptions supporting any sample
9			
10			size calculations
11			
12			
13	Recruitment	#15	Strategies for achieving adequate participant enrolment to 4
14			
15			
16			reach target sample size
17			
18			
19	Methods:		
20			
21	Assignment of		
22			
23	interventions (for		
24			
25	controlled trials)		
26			
27			
28			
29	Allocation: sequence	#16a	Method of generating the allocation sequence (eg, 4-5
30	generation		
31			computer-generated random numbers), and list of any
32			
33			factors for stratification. To reduce predictability of a
34			
35			random sequence, details of any planned restriction (eg,
36			
37			blocking) should be provided in a separate document that
38			
39			is unavailable to those who enrol participants or assign
40			
41			interventions
42			
43			
44			
45	Allocation	#16b	Mechanism of implementing the allocation sequence (eg, 4-5
46	concealment		
47			central telephone; sequentially numbered, opaque, sealed
48			
49	mechanism		envelopes), describing any steps to conceal the sequence
50			
51			until interventions are assigned
52			
53			
54			
55	Allocation:	#16c	Who will generate the allocation sequence, who will enrol 4-5
56	implementation		
57			participants, and who will assign participants to
58			
59			
60			

1		interventions	
2			
3			
4	Blinding (masking)	#17a Who will be blinded after assignment to interventions (eg,	4-5
5		trial participants, care providers, outcome assessors, data	
6		analysts), and how	
7			
8			
9			
10			
11	Blinding (masking):	#17b If blinded, circumstances under which unblinding is	4-5
12		emergency	
13		permissible, and procedure for revealing a participant's	
14	unblinding	allocated intervention during the trial	
15			
16			
17			
18			
19	Methods: Data		
20			
21	collection,		
22			
23	management, and		
24			
25	analysis		
26			
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28			
29	Data collection plan	#18a Plans for assessment and collection of outcome,	7
30		baseline, and other trial data, including any related	
31		processes to promote data quality (eg, duplicate	
32		measurements, training of assessors) and a description of	
33		study instruments (eg, questionnaires, laboratory tests)	
34		along with their reliability and validity, if known. Reference	
35		to where data collection forms can be found, if not in the	
36		protocol	
37			
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48	Data collection plan:	#18b Plans to promote participant retention and complete	7
49	retention	follow-up, including list of any outcome data to be	
50		collected for participants who discontinue or deviate from	
51		intervention protocols	
52			
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58	Data management	#19 Plans for data entry, coding, security, and storage,	7
59			
60			

including any related processes to promote data quality
(eg, double data entry; range checks for data values).

Reference to where details of data management
procedures can be found, if not in the protocol

10 Statistics: outcomes [#20a](#) Statistical methods for analysing primary and secondary 8-9
11
12 outcomes. Reference to where other details of the
13
14 statistical analysis plan can be found, if not in the protocol

18 Statistics: additional [#20b](#) Methods for any additional analyses (eg, subgroup and 8-9
19
20 analyses adjusted analyses)

23 Statistics: analysis [#20c](#) Definition of analysis population relating to protocol non- 8-9
24
25 population and adherence (eg, as randomised analysis), and any
26
27 missing data statistical methods to handle missing data (eg, multiple
28
29 imputation)

33 Methods: Monitoring

36 Data monitoring: [#21a](#) Composition of data monitoring committee (DMC); 7
37
38 formal committee summary of its role and reporting structure; statement of
39
40 whether it is independent from the sponsor and
41
42 competing interests; and reference to where further
43
44 details about its charter can be found, if not in the
45
46 protocol. Alternatively, an explanation of why a DMC is
47
48 not needed
49
50
51

53 Data monitoring: [#21b](#) Description of any interim analyses and stopping 7
54
55 interim analysis guidelines, including who will have access to these
56
57 interim results and make the final decision to terminate
58
59

1		the trial	
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3			
4	Harms	#22 Plans for collecting, assessing, reporting, and managing	7
5		solicited and spontaneously reported adverse events and	
6		other unintended effects of trial interventions or trial	
7		conduct	
8			
9			
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11			
12			
13	Auditing	#23 Frequency and procedures for auditing trial conduct, if	7
14		any, and whether the process will be independent from	
15		investigators and the sponsor	
16			
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20			
21	Ethics and		
22	dissemination		
23			
24			
25			
26	Research ethics	#24 Plans for seeking research ethics committee / institutional	10
27	approval	review board (REC / IRB) approval	
28			
29			
30			
31	Protocol	#25 Plans for communicating important protocol modifications	10
32	amendments	(eg, changes to eligibility criteria, outcomes, analyses) to	
33		relevant parties (eg, investigators, REC / IRBs, trial	
34		participants, trial registries, journals, regulators)	
35			
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41	Consent or assent	#26a Who will obtain informed consent or assent from potential	10
42		trial participants or authorised surrogates, and how (see	
43		Item 32)	
44			
45			
46			
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48			
49	Consent or assent:	#26b Additional consent provisions for collection and use of	Not
50	ancillary studies	participant data and biological specimens in ancillary	applicable
51		studies, if applicable	
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57	Confidentiality	#27 How personal information about potential and enrolled	7
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participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial

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8	Declaration of	#28	Financial and other competing interests for principal
9			
10	interests		investigators for the overall trial and each study site
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13	Data access	#29	Statement of who will have access to the final trial
14			
15			dataset, and disclosure of contractual agreements that
16			
17			limit such access for investigators
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21	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for
22			
23	trial care		compensation to those who suffer harm from trial
24			
25			participation
26			
27			
28	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial
29			
30	trial results		results to participants, healthcare professionals, the
31			
32			public, and other relevant groups (eg, via publication,
33			
34			reporting in results databases, or other data sharing
35			
36			arrangements), including any publication restrictions
37			
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39			
40			
41	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of
42			
43	authorship		professional writers
44			
45			
46	Dissemination policy:	#31c	Plans, if any, for granting public access to the full
47			
48	reproducible		protocol, participant-level dataset, and statistical code
49			
50			
51	research		
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53			
54	Appendices		
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57	Informed consent	#32	Model consent form and other related documentation
58			
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1 materials given to participants and authorised surrogates
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4 Biological specimens [#33](#) Plans for collection, laboratory evaluation, and storage of Not
5
6 biological specimens for genetic or molecular analysis in applicable
7
8 the current trial and for future use in ancillary studies, if
9
10 applicable
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13 None The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative
14 Commons Attribution License CC-BY-NC. This checklist can be completed online using
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18 [Penelope.ai](#)
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Internal brace augmentation reconstruction VS standard anterior cruciate ligament reconstruction:A randomized controlled clinical trial study protocol.

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Manuscripts

1 Internal brace augmentation reconstruction VS 2 standard anterior cruciate ligament reconstruction : 3 A randomized controlled clinical trial study protocol.

4
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19 20 **Abstract:**

21 **Introduction:** Anterior cruciate ligament (ACL) rupture is one of the most common
22 knee injuries in sports, and the gold standard for treating ACL rupture is tendon graft
23 reconstruction. Recently, internal brace technology has been gradually applied to
24 ligament repair, but there is still need to be more relevant in vivo clinical evidence for
25 using internal brace technology in ACL reconstruction (ACLR). We conducted a
26 randomized controlled trial to investigate the clinical efficacy of internal brace
27 technology in ACLR.

28 **Methods and analysis:** This is a randomized, parallel controlled trial of patients with
29 ACL rupture who underwent inpatient surgery at the Department of Orthopedics,
30 Xiangya Hospital, Central South University. All study subjects were assigned to the
31 test and control groups according to the random number table method. The test group
32 underwent ACLR using the internal brace technique, and the control group underwent
33 standard ACLR, with uniform postoperative rehabilitation in both groups. Patient-
34 reported outcomes were preoperative baseline and postoperative recovery at 1, 3, 6, 12,
35 and 24 months. The primary outcome was International Knee Documentation
36 Committee (IKDC) function from baseline (ACL rupture) to 6 months postoperatively.
37 Secondary outcomes included (I) other patient outcome reporting metrics, the Lysholm
38 knee score (LKS), the Knee Injury and Osteoarthritis Outcome Score (KOOS), and the
39 Visual Analog Scale (VAS), (II) the use of the Kneelax3 knee stabilizer to assess knee

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3 40 stability, (III) the occurrence of adverse events, such as graft refraction or symptomatic
4 41 instability, postoperative infection, and contralateral injury, and (IV) magnetic
5 42 resonance images at 12 and 24 months after ACLR.

7 43 **Ethics and dissemination:** This trial was approved by the Medical Ethics Committee
8 44 of Xiangya Hospital of Central South University on October 26, 2021. Data will be
9 45 published in peer-reviewed journals and presented at national and international
11 46 conferences.

12 47 **Trial registration number:** ChiCTR2200057526.

14 48 **Strengths and limitations of this study:**

- 16 49 • This study aims to demonstrate the clinical superiority of the Internal brace compared
17 50 to conventional ACL reconstruction (ACLR) through a 2-year follow-up period.
- 19 51 • This study will fill an existing gap regarding the efficacy of the internal brace in ACL
20 52 reconstruction by providing robust and high-quality evidence on its role and impact.
- 22 53 • The study has a standard and detailed rehabilitation program to ensure a smooth
23 54 recovery after ACLR.
- 25 55 • This trial was conducted in a single centre, and data lacked generalizability.

27 56 **Keywords:**

28 57 Anterior cruciate ligament (ACL), Anterior cruciate ligament reconstruction (ACLR),
29 58 Internal brace, Study protocol.

31 59 **Introduction**

33 60 A 41-year-old miner successfully performed the world's first ACL repair surgery, and
34 61 the function of the knee joint was very good after surgery¹. ACL rupture is one of the
35 62 most common ligament injuries in the knee, mainly in young people who participate in
36 63 sports. If not actively treated after injury, joint instability and other phenomena often
37 64 occur, reducing the quality of life and increasing the risk of osteoarthritis²⁻⁴. Over the
38 65 past few decades, ACL ruptures have been estimated at approximately 30 to 52 cases
39 66 per 100,000 person-years⁵. ACL injuries occur in more than 175,000 people in the
40 67 United States annually, and approximately 100,000 undergo surgery⁶⁻⁸. With the
41 68 continuous development of surgical techniques, the current mainstream surgical
42 69 method is to perform ACLR under arthroscopy⁹. In recent years, a Japanese study found
43 70 that for rugby players under the age of 20 after ACLR, the re-disruption rate of ACLR
44 71 grafts after returning to the field was 23%¹⁰. At the same time, other studies have also
45 72 shown that the revision rate of ACLR with an allogeneic tendon in adolescents can
46 73 reach 35%¹¹; however, the effect after revision is not as good as that of primary ACLR¹².

48 74 Internal brace technology was promoted in 2010, which uses braided ultrahigh
49 75 molecular weight polyethylene (UHMWPE) polyester suture tape and knotless bone
50 76 anchors to reinforce ligament strength, also known as an auxiliary stabilizing structure
51 77 for recovery of motion after ligament repair, which helps prevent secondary damage,
52 78 ¹³such as anterior and posterior cruciate ligament, medial and lateral collateral ligament
53 79 repair of the knee¹³⁻¹⁵, and ankle and elbow ligament strengthening repair^{16 17}. Enhanced
54 80 collateral ligament repair and reconstruction with an internal brace improve limb
55 81 biomechanics, including greater stiffness and maximum load, while facilitating early

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3 82 rehabilitation in the motor and biomechanical environment^{12 14}. Reinforced ligament
4 83 repair offers unique advantages over traditional reconstruction techniques, including
5 84 smaller bores and implants, no risk of disease transmission from allografts, and no risk
6 85 of tunnel convergence during the procedure^{14 18 19}. Therefore, ACL reinforcement is an
7 86 alternative method for supporting ACL grafts synergistically, load-sharing manner with
8 87 primary tension on the graft and high-strength suture tape.

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10
11 88 In the case of ACLR, the internal brace ligament augmentation technique helps prevent
12 89 various failure scenarios, including creep and irreversible stretching, traumatic tears,
13 90 and slippage of the tendon-bone interface^{20 21}. In addition, these failures can be avoided
14 91 when the graft is small or vulnerable^{20 21}. In 2018, in an in vitro trial, Dr Pat Smith
15 92 found that ACLR combined with independent suture tape significantly reduced graft
16 93 elongation and allowed the grafted ligaments to accept higher ultimate disruption loads,
17 94 thereby reducing the risk of re-rupture of the graft²⁰. Preliminary short-term studies
18 95 have shown that using the internal brace technique can significantly improve functional
19 96 recovery after ACLR and improve patient quality of life. However, only a few medical
20 97 institutions use ACLR combined with the internal brace technique, and there needs to
21 98 be more relevant in vivo clinical evidence.

22
23
24 99 This study will fill this gap by exploring whether internal brace technology can improve
25 100 the outcome of patients with ligament injuries and provide a new option for patients
26 101 with ACL injuries.

27 28 102 **Methods and analysis**

29 30 103 **Study setting**

31
32 104 This was a randomized parallel-controlled trial conducted under the guidance of the
33 105 CONSORT statement²² and included patients with ACL rupture who were hospitalized
34 106 in the Department of Orthopedics at Xiangya Hospital of Central South University from
35 107 01/03/2022 to 28/02/2023. The Medical Ethics Committee of Xiangya Hospital of
36 108 Central South University approved the ethical application related to this study and has
37 109 filed it (ethical approval number: 202110478). All subjects signed the informed consent
38 110 form before the operations.

39 40 111 **Eligibility criteria**

41
42 112 The inclusion criteria are as follows: (1) age of 16-45 years; (2) unilateral knee MRI
43 113 showing unilateral knee ACL fracture; (3) combined meniscal injury that does not
44 114 interfere with the standard postoperative rehabilitation program after intraoperative
45 115 management; (4) combined grade III or lower cartilage injury that does not interfere
46 116 with the standard postoperative rehabilitation program; (5) meet the 24 months of
47 117 follow-up; (6) no previous injury to the healthy knee; (7) informed consent of the
48 118 subject and signing of relevant documents.

49
50
51 119 The exclusion criteria are as follows: (1) age of <16 years or >45 years; (2) previous
52 120 ACLR or bilateral ACL injury; (3) MRI revealed posterior cruciate ligament (PCL),
53 121 medial collateral ligament (MCL), or lateral collateral ligament (LCL) injury; (4) grade
54 122 IV cartilage injury or unstable longitudinal meniscus tear requiring repair that interferes
55 123 with standard rehabilitation protocols after surgical management; (5) patients who
56 124 cannot meet 24 follow-up visits; (6) patients with severe underlying medical conditions
57 125 that make surgery inadvisable, or patients with mental illness, pregnancy during
58 126 planned trials, or other conditions that are not conducive to late follow-up.

127 **Participant selection:**

128 Patients diagnosed with ACL rupture by clinicians through physical examination and
129 MRI imaging evaluation were randomly allocated to the trial and control groups after
130 final confirmation of ACL rupture under arthroscopy and agreeing to participate in this
131 study. The trial group was reconstructed using ACLR with the internal brace technique,
132 and the control group was reconstructed using ACLR without the internal brace
133 technique. Preoperative assessment of patients was performed before surgery, and a
134 uniform rehabilitation program was performed after surgery. The protocol (version 1.0,
135 March 2022) inclusion start date was March 2022, with an expected cutoff date of
136 March 2023. The follow-up period is 2 years, with the last follow-up expected in March
137 2025 (the exact end date is based on the inclusion of the last subject), and the specific
138 technical route is shown in **Fig. 1**.

139 **Study sample**

140 IKDC score consists of three aspects: 1) symptoms, including pain, stiffness, swelling,
141 interlocking/jamming, and softening legs; 2) motion and daily activities; and 3) Current
142 knee function, but knee function prior to knee injury does not count towards the total
143 score, which is the main outcome indicator of this study, based on which the sample
144 size required for this trial was estimated. IKDC scores are continuous measurement
145 data, and this study compares statistical differences between the means \pm standard
146 deviations of the two groups. The minimum clinically important difference (MCID) of
147 the IKDC scale was reported to be between 8.8 and 15.6²³⁻²⁵, we set δ to 10, and the
148 overall sample standard deviation was set to 13 based on the relevant literature²³⁻²⁵. To
149 satisfy the power of a test ($1-\beta$, β means type II error) of 0.8 and the test level α (type I
150 error) of 0.05, the sample size calculated for each group was 27 according to the
151 following formula, and considering a 20% lost visit rate, 33 patients were included in
152 each group with a total of 66 patients included.

153 **Randomization and Concealed Grouping**

154 Using a computer-generated random number list, all eligible subjects were randomly
155 assigned in a 1:1 ratio to the ACLR the endoprosthesis technique group (combined
156 group, n=33) and the standard ACL reconstruction group (simple group, n=33) after
157 screening by inclusion and exclusion criteria, with no restrictions on either study group.
158 Randomization was carried out by an investigator who was not further involved in the
159 study. The allocation results were sealed in opaque envelopes and kept by the study
160 coordinator. On the day of surgery, one envelope per patient was given to the surgeon
161 by the study coordinator. Subjects and physicians included in the study were informed
162 of the grouping, but neither the rehabilitators who instructed the patients on
163 rehabilitation nor the data collectors who conducted the follow-up visits were aware of
164 the grouping of the patients.

165 **Interventions and surgical techniques**

166 In all cases, all inside ACLR was performed using autologous semitendinosus tendons
167 with the arthroscopy. Semitendinosus tendons were braided with sutures (0 FiberWire
168 Suture, Arthrex) to form four strands of ACL grafts (all between 7.5 and 10 mm in
169 diameter, supplemented with semimembranous tendons less than 7.5 mm in diameter).
170 In the ACLR group, the braided graft femoral end and tibial segment were suspended
171 and fixed with a TightRope (ACL TightRope RT Implant, Arthrex), and in the ACLR

172 with internal brace group, a separate wire tape (2 mm FiberTape, Arthrex) was added
 173 to the ACLR group. The suture was fixed with a knotless bone anchor (4.75-mm PEEK
 174 SwiveLock, Arthrex) distally and a TightRope suspension proximally as in the graft—
 175 fig. 2.

176 The procedure was as follows: the patient was anaesthetized, a tourniquet was applied
 177 to the affected limb, routine surgical disinfection of the knee was performed, a sterile
 178 surgical sheet was placed, the semitendinosus tendon was palpated, a straight incision
 179 was made medial to the tibial tuberosity, the semitendinosus tendon was removed with
 180 a tendon extractor, 10 ml of ropivacaine was injected at the tendon extraction site, and
 181 then, the removed semitendinosus tendon was braided into 4 strands using the
 182 GraftLink (Arthrex) technique²⁶. A conventional knee arthroscopic approach was
 183 performed on the anteromedial and anterolateral sides of the affected knee to explore
 184 the injured structures and remove the remaining portion of the ACL. The knee was
 185 flexed to the extreme, and the femoral tract was created at the footprint of the ACL stop
 186 at the lateral femoral condyle and the tibial tract at the footprint of the ACL start. The
 187 graft and two TightRope titanium plates were pulled into the knee cavity and pulled out
 188 through the femoral and tibial tracts, respectively. The tabs were flipped, the tab rings
 189 were tightened, and the titanium plates were fixed. In the ACLR with an internal brace
 190 group, the femoral end of the FiberTape wire band was fixed with a TightRope ring,
 191 the wire band was tensioned in the extended position, and the tibial end was fixed
 192 independently with a knotless bone anchor (4.75-mm PEEK SwiveLock, Arthrex).

193 All patients received a uniform training and rehabilitation program after surgery, and
 194 the entire rehabilitation process was divided into 7 phases. The first 3 phases focused
 195 on controlling swelling and restoring range of motion, which usually required 4 weeks.
 196 A detailed rehabilitation plan can be found in **Table 1**. Phases 4-5 focused on restoring
 197 quadriceps muscle strength control and balance and core strength restoration training,
 198 and phases 6-7 were gradually resumption of various sports activities, from daily
 199 activities to professional activities or contact sports. A detailed rehabilitation plan can
 200 be found in **Table 2** and **Table 3**.

201 **Table 1. Phases 1-3 of the post-ACLR rehabilitation program**

Phase	Movement Exercises	Gait Exercises	Manipulative Massage	Rehabilitation Goals	Precautions
Phase 1 (within 1 week)	(1) Bed heel against the bed for flexion and extension sliding; supine position, the affected leg bends the hip, flexes the knee and places the heel on the wall for flexion and extension sliding; sitting position, legs on the floor; the healthy leg is placed in front of the affected leg and assists the affected leg in flexing the knee. (2) Ankle pump exercises (the affected leg is elevated, and the foot performs upward hooking and downward stepping movements, and rotational movements). (3) Anterior thigh muscle tensing exercises with the knee in the straight position (can be combined with neuromuscular electrical stimulation or biofeedback exercises). (4) Hip muscle group training. (5) Pillow clamping of the legs for medial	(1) Flat and step gait training with the support of a knee protection brace and double crutches. (2) Cold compresses after training to reduce oedema.	(1) Push the patella in all directions. (2) Manipulation of the posterior thigh muscles of the affected limb or sitting and standing to pull the muscles to relieve	Active mobility of the knee joint reaches 0° to 90°. (1) The anterolateral thigh muscles can be tightened better. (2) The affected limb can be fully weight-bearing with the help of braces and crutches.	(1) Brace locked in 0° position, crutches, and weight-bearing exercises within a tolerable range. (2) Wear the brace at night and lock it in the 0° position while sleeping with the affected leg elevated.

	<p>thigh muscle group strength training.</p> <p>(6) The brace is locked in the 0° position, and the affected leg is lifted in the supine, prone and prone positions for muscle strength training.</p> <p>(7) Passive knee extension exercises: prone position with the affected knee extended out of bed for suspension or supine position with the affected leg in a slightly elevated heel position and the knee joint suspended.</p> <p>(8) weight transfer training (front-to-back and left-to-right) can be performed in the above weight-bearing exercise position.</p> <p>(9) Continuous passive movement apparatus training with increased knee flexion by 5°to 10°/day.</p>		<p>their spasm.</p>	<p>(3) Edema control is good.</p> <p>(4) Good wound healing.</p>	
Phase 2 (1-2 weeks)	<p>(1) Fixed cycling exercises (from small to a full range of pedal rotation).</p> <p>(2) Tightening and 90° muscle strength exercises for the anterior thigh muscles in the straight position.</p> <p>(3) Standing balance training on the affected leg with a single leg wearing a support.</p> <p>(4) Balance training on a balance board with forward and backward weight transfer.</p> <p>(5) Continuous passive activity equipment training.</p> <p>(6) Start small partial weight-bearing squat exercises (within 30° of knee flexion).</p> <p>(7) Passive straightening exercises with the heel slightly elevated and the knee hanging in the air.</p> <p>(8) Straight leg raises training (all directions).</p> <p>(9) Terminal angle knee extension training in the standing position using an elastic band.</p>	<p>(1) The healthy leg stands outside the treadmill with weight, and the affected leg simulates walking on the treadmill.</p> <p>(2) The affected leg crosses the obstacle training and simulates walking.</p>	<p>(1) Manipulation to push the patella treatment.</p> <p>(2) Manipulation of the posterior thigh muscle group for relaxation and stretching exercises.</p>	<p>The active mobility of the knee joint reaches 0°to 120°.</p> <p>(1) Straight leg elevation; anterior thigh muscles can be tightened with force.</p> <p>(2) the patient can walk normally with crutches with a nonlocking brace.</p>	<p>(1) Weight-bearing exercises within tolerable limits.</p> <p>(2) Transition from double to single crutch.</p> <p>(3) When the strength of the anterior thigh muscle group is well exercised, the locking brace can be gradually dispensed (the anterior thigh muscle group can be unlocked to more than 30° only when it can contract forcefully to keep the straight leg elevated).</p>
Phase 3 (2-4 weeks)	<p>(1) Fixed bicycle training gradually increases the resistance to improve exercise endurance.</p> <p>(2) Tightening exercises for the anterior thigh muscle group in the straight position and muscle strength exercises in the range of 60°to 90° until the muscle strength of both legs is equal.</p> <p>(3) 0°to 60° squat training, gradually increasing the resistance strength (for patients with meniscal repair, squat to the target angle on the healthy leg before shifting the weight to the middle of the two legs).</p> <p>(4) Stand with both legs on a balance board for balance training in multiple directions.</p> <p>(5) Single-leg standing balance training on the affected leg (with eyes closed and open and on a support surface with different degrees of softness).</p> <p>(6) Straight leg raise training in the standing position can increase resistance appropriately.</p>	<p>Exercise with a rope tied around the waist or on a treadmill for forward and backward gait training.</p>	<p>(1) Manipulation to push the patella treatment.</p> <p>(2) Manipulation of the surgical scar.</p> <p>(3) Manipulative passive knee flexion or extension angle exercises.</p>	<p>The knee joint moves to an active full angle, aligning with the healthy side leg.</p> <p>(1) Normal gait can be achieved without any walking aid.</p> <p>(2) Self-care of daily life (may have difficulty walking up and down steps).</p>	<p>Fully weight bearing; normal gait can be achieved without a brace or walker at 3 weeks postoperatively.</p>

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Table2: Phases 4-5 of the post-ACLR rehabilitation program

Phase	Movement Exercises	Gait Exercises	Manipulative Massage	Rehabilitation Goals	Precautions
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Phase 4 (4-8 weeks)	<p>(1) Fixed cycling training: gradually increasing the resistance.</p> <p>(2) Squat training: Double leg transition to a single leg (0° to 60°), gradually increasing resistance.</p> <p>(3) Lunge training (0° to 60°).</p> <p>(4) Step training: centripetal and centrifugal contraction of the anterior thigh muscles (knee does not exceed 60°).</p> <p>(5) Tiptoe training: Double leg transition to a single leg.</p> <p>(6) Swing exercise: The affected leg stands on one leg, and the healthy leg is strapped with an elastic band and swings, transitioning from front-to-back swing to lateral swing and then to rotation or random direction movement.</p> <p>(7) Rotational stability training: static lunge stance, lateral pull pulley exercise.</p> <p>(8) Exercise with a rope tied around the waist to provide resistance; walking exercises in the forward and backward, left and right directions.</p> <p>(9) Walking exercises on the treadmill in 4 directions.</p> <p>(10) Balance board training: various of support surfaces, double-legged standing.</p> <p>(11) Single-leg stand for ball tossing exercises.</p> <p>(12) Core training: supine or prone position for bridge exercise, standing to pull pulley.</p>	Go around obstacles at normal walking speeds on different surfaces.	Manual method to loosen surgical scars.	<p>(1) Center of gravity in the middle, squatting bilaterally to 60° (no more than 60°).</p> <p>(2) Knee in good condition (slight pain and effusion, no instability).</p> <p>(3) The circumference at the upper edge of the patella is 10 cm, within a 1 to 2 cm difference between the legs.</p> <p>(4) The affected limb can maintain balance for > 30 seconds while standing on one leg with little body sway.</p>	<p>(1) Do not participate in sports with a high impact on the joints, such as running or jumping.</p> <p>(2) Do not participate in sports with high lateral stress on the joints.</p> <p>(3) Avoid squatting deeply (limit to 0° to 60°).</p>
Phase 5 (8-12 weeks)	<p>(1) Squat training: transition from double to single leg (0° to 60°), gradually increasing resistance.</p> <p>(2) Lunge training (0° to 60°).</p> <p>(3) Tiptoe training: double-leg transition to single-leg.</p> <p>(4) Increasing the strength of the posterior lateral muscle group with plyometric training.</p> <p>Core muscle strength training.</p> <p>① Combined strength training with balance training (throwing and catching balls on the balance board, small squats on the balance board, etc.)</p> <p>② Advanced balance function training (affected leg standing on one leg, hand or opposite foot to touch objects on the ground or lateral pulling elastic band)</p> <p>③ Swimming training, in addition to breaststroke. Additionally, care should be taken not to stir the leg at a deep squatting angle or to use a splint when swimming.</p> <p>④ Cycling training every other day.</p>	—	—	<p>(1) The thigh circumference of both legs is close to the same (within 1 cm of each other).</p> <p>(2) The affected limb squats to 60° on one leg.</p> <p>(3) The affected limb can stand on one leg to maintain balance for 60 seconds.</p> <p>(4) Little, if any, oedema with activity.</p>	Patellar tendonitis may occur.

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Table 3: Phases 6-7 of the post-ACLR rehabilitation program

Phase	Movement Exercises	Gait Exercises	Manipulative Massage	Rehabilitation Goals	Precautions
Phase 6 (12-16 weeks)	<p>(1) Jogging movement: multiple directions for running</p> <p>(2) Increasing the speed of all sports.</p> <p>(3) Skateboard training, slow walking in the water and other forms of exercise can be carried out.</p>	—	—	<p>(1) Squat down to 60° on one leg with the affected limb and repeat 20 times.</p> <p>(2) The affected leg can stand on one leg to maintain balance for at least 60 seconds.</p> <p>(3) Vertical or horizontal jump with both legs with a good landing position.</p> <p>(4) Single-leg jump: 80% of the ability of the healthy leg is achieved.</p>	<p>Avoid wrong movements or posture.</p> <p>(1) Landing with the knee joint too straight.</p> <p>(2) The knee joint is turned outward or inward when landing.</p> <p>(3) When landing or bouncing, the healthy leg always takes the lead, and the affected leg does not.</p>

Phase 6 (12-16 weeks)

(1) Jogging movement: multiple directions for running.
 (2) Increasing the speed of all sports.
 (3) Skateboard training, slow walking in the water and other forms of exercise can be carried out.

(1) Squat down to 60° on one leg with the affected limb and repeat 20 times.
 (2) The affected leg can stand on one leg to maintain balance for at least 60 seconds.
 (3) Vertical or horizontal jump with both legs with a good landing position.
 (4) Single-leg jump: 80% of the ability of the healthy leg is achieved.

Avoid wrong movements or posture.
 (1) Landing with the knee joint too straight.
 (2) The knee joint is turned outward or inward when landing.
 (3) When landing or bouncing, the healthy leg always takes the lead, and the affected leg does not.

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209 **Baseline indicators and observations**

210 Baseline and preoperative patient characteristics included the subject's sex, age,
 211 affected limb (left or right), cause of injury (playing basketball, other sports such as
 212 soccer), smoking status (yes or no), time from injury to surgery (fresh injury or old
 213 rupture), whether the injury was accompanied by cartilage and meniscal damage, time
 214 of surgery, and degree of ACL fracture (partial or total).

215 **Study endpoints**

216 **Primary outcome/endpoint:** The IKDC scores changes in knee function from
 217 preoperative to 6 months postoperative. The IKDC is a commonly used tool to evaluate
 218 outcomes after knee surgeries, including ACLR²⁷. The IKDC knee score consists of a
 219 knee assessment (10 entries) and a knee ligament checklist (8 entries), covering joint
 220 pain, motor level and daily activity ability, with a total score of 0 to 100. The IKDC can
 221 address knee symptoms, function and physical activity. The IKDC assesses symptoms,
 222 function and physical activity of the knee. Patients were evaluated with the
 223 questionnaire preoperatively and at follow-up visits at 1, 3, 6, 12, and 24 months
 224 postoperatively.

225 **Secondary outcomes/endpoints:** LKS, KOOS (including knee symptoms, pain,
 226 activities of daily living, sports and recreational activities, and quality of life), VAS
 227 (For pain assessment), Lachman test, MRI imaging data, and assessment of knee
 228 stability using the Kneelax3 knee stability meter.

229 (1) Kneelax3 (MONITORED REHAB SYSTEMS B.V. Model: KNEELAX3, The
 230 Netherlands): preoperatively and 1, 3, 6, 12 and 24 months postoperatively; the
 231 Kneelax3 arthrometer was used for the assessment of knee stability.

232 (2) LKS: This scoring system consists of 8 questions on a scale of 0-100, with higher
 233 scores representing a better patient's functional status. The main tendency is toward
 234 activities of daily living, and patients were assessed by questionnaires before surgery
 235 and at 1, 3, 6, 12, and 24 months of postoperative follow-up visits²⁸.

236 (3) KOOS score: The KOOS consists of 5 subscales: pain, other knee symptoms,
 237 activities of daily living (ADL), function in sport and recreation (Sport/Rec), and knee-
 238 related quality of life (QOL)²⁹. Patients were given one week to consider before
 239 answering the questions, and each question had five alternative boxes with scores
 240 ranging from 0 to 4. Standard scores were calculated for each subscale (100 for no

241 symptoms and 0 for extreme symptoms), and patients were assessed with
242 questionnaires before surgery and at follow-up visits at 1, 3, 6, 12, and 24 months after
243 surgery.

244 (4) VAS score: The visual analogue pain scoring method is more sensitive and
245 comparable. In this trial, a 100-mm VAS pain score (including resting state score, 30-
246 min post-walk score and overall pain level in the past month) was used³⁰. This protocol
247 only assesses pain at rest, with 0 representing no pain and 100 representing the most
248 severe pain. Patients were evaluated with questionnaires at preoperative and
249 postoperative follow-up visits at 1, 3, 6, 12, and 24 months.

250 (5) Lachman test: This assesses ACL function with the patient in the supine or prone
251 position with the knee flexed at approximately a 30° angle³¹. The examiner uses one
252 hand to immobilize the thigh while the other attempts to move the tibia forward.
253 Positive results suggest that patients with ACL injuries be tested preoperatively and at
254 follow-up visits at 1, 3, 6, 12, and 24 months postoperatively.

255 (6) MRI assessment: MRI was performed at 12 and 24 months postoperatively to assess
256 the patient's reconstructed ACL.

257 **Patient termination and withdrawal criteria**

258 Patients may withdraw from this trial at any time. Patients may withdraw from the study
259 for the following reasons.

260 **(1) Surgical failure:** 1) occurrence of infection, 2) no secondary rupture of the
261 reconstructed ligament (rupture of the ligament, rupture of the internal brace
262 augmentation line and both in the trial group, rupture of the reconstructed ligament in
263 the control group), 3) knee instability: patient self-reported knee instability, or Lachman
264 test (+) or Kneelax3 knee arthrometer test revealed a 3-mm difference in comparison
265 with the healthy side.

266 **(2) Patient withdrawal from the trial:** All subjects had the right to withdraw at any
267 time during the study. A subject was withdrawn from the trial if any of the following
268 occurred during the trial: 1) withdrawal of informed consent by the subject; 2) a person
269 who, in the opinion of the investigator, is no longer suitable for continuation of the
270 clinical trial; 3) a woman who becomes pregnant during the clinical trial; 4) death of
271 the subject; or 5) the subject is lost to follow-up.

272 **(3) Trial termination:**

273 1) The clinical trial institution and the investigator found that the risks to patients of
274 continuing the clinical trial exceed the possible benefits; 2) the ethics committee finds
275 that the rights of the subjects cannot be protected; 3) the sponsor requests termination
276 of the trial for various reasons; and 4) the national administrative authority requests
277 termination.

278 The timing and reasons for withdrawal from the trial were recorded in detail on the case
279 report form; follow-up care is no longer provided for subjects who voluntarily withdraw
280 from the treatment as well as for those for whom follow-up data are not being collected,
281 but subjects who withdrew from the trial due to adverse events or because of surgical
282 failure must be followed up until the adverse events stabilized or resolved or until the
283 investigator deemed that further follow-up was no longer necessary.

284 **Data management**

285 The trial used an electronic data collection (EDC) system for data management. The
286 investigator or investigator-authorized research staff completed the electronic Case
287 Report Form (eCRF) through the EDC system in an accurate, timely, complete and
288 standardized manner based on the original information from the subjects. Questionnaire
289 checking, data cleaning and summarization were performed in a promptly after each
290 follow-up visit. The follow-up survey is proposed to adopt the electronic questionnaire
291 system and on-site questionnaire survey, and the on-site survey results will be saved in
292 time and organized in the database later. The investigator or the investigator's
293 authorized researcher enters the data into the EDC according to their respective
294 accounts. The data administrator verifies the data's reliability, completeness, and
295 accuracy in the EDC. If any questionable data are found, a challenge can be issued in
296 the system, and the investigator or the investigator's delegated researcher verifies,
297 corrects, or answers the query. When all data have been entered into the database, and
298 all queries have been resolved, the database will be locked by the data administrator. If
299 a problem is found after the database is locked and there is a need to correct it, the
300 process of unlocking and relocking the data should be followed. After the database is
301 locked, the data manager submits the data to the statistical analyst for statistical analysis
302 as scheduled.

303 **Statistical analysis**

304 **(1) Statistical design:** This trial was a randomized controlled clinical trial.

305 **(2) Principles of Statistical Analysis:** All statistical analyses were performed in SAS
306 version 9.4 or later, R version 3.3.2 or later, or SPSS24. All statistical tests were
307 performed using two-sided tests, and P values less than or equal to 0.05 were considered
308 statistically significant for the differences tested (unless otherwise specified).

309 1) Summary statistics for continuous variables: including the mean, standard deviation,
310 median, minimum, maximum, lower quartile (Q1), and upper quartile (Q3); summary
311 statistics for categorical variables, including the number of cases and percentage of each
312 category.

313 2) Between-group comparisons of demographic baseline characteristics: Group
314 comparisons for continuous variables will be made using independent samples t-test
315 (chi-square, normal distribution) or Wilcoxon rank sum test depending on data
316 distribution, and the chi-square test or the exact probability method for categorical
317 variables (if chi-square test is not applicable).

318 **(3) Completion and demographic analyses**

319 Baseline analyses were based on the full analysis set (FAS). The enrollment and
320 completion status of the trials were summarized, and the reasons for noncompletion are
321 described in a detailed table. Subjects' demographic characteristics were described and
322 compared to measure the comparability of the two groups. Validity reporting data were
323 accepted only if the baseline was balanced between groups; otherwise, validity data
324 were subject to correction before reporting.

325 **(4) Patient-reported outcome validity evaluation indices**

326 The outcome validity evaluation will be based on the FAS and the per-protocol set
327 (PPS). The statistical description and inference of the data will be based on the

328 characteristics of the data and the selection of applicable descriptive indicators and
329 hypothesis testing methods.

330 **Primary patient-reported outcome:** comparison of IKDC knee scores at 6 months
331 (± 2 weeks) postoperatively in the trial and control groups. We will use a linear
332 regression model for analysis to correct for possible confounding factors, such as age,
333 sex, and cause of injury. Preoperative baseline IKDC scores were used as predictors
334 when conducting the analysis, and IKDC at 6 months (± 2 weeks) was used as an
335 indicator of posttreatment outcomes.

336 **Secondary patient-reported outcomes**

337 1) Because IKDC scores were measured multiple times during patient follow-up, we
338 used a linear mixed model to compare changes over time between the trial and control
339 groups.

340 2) Anterior tibial translation distance is measured by the Kneelax3 knee stability meter,
341 and comparisons of anterior tibial translation distance between the test and control
342 groups at the same postoperative time points with the same force will be performed
343 using either an independent samples t-test (chi-square, normally distributed) or a
344 Wilcoxon rank sum test. A linear mixed model will also be used to compare and analyze
345 the evolution of these consecutive results over time in both groups.

346 3) Here, the comparative analysis of failure rate and infection rate in the control group
347 versus the test group during the main 6 months will be performed using the chi-square
348 test or the t-test.

349 4) Linear regression of continuous outcomes from baseline to 24 months, such as the
350 LKS, KOOS score (including knee symptoms, pain, activities of daily living, sports and
351 recreational activities, quality of life), Lachman test, and pain visual analogue score
352 (VAS) protocols, will be used to compare and analyze the evolution of these continuous
353 outcomes over time in the two groups using linear mixed models.

354 5) The morphology and signal intensity of the postoperative ACL will be assessed using
355 MRI methods, and the different treatments will be compared at different time points
356 using chi-square tests.

357 **Analysis of safety indicators**

358 The safety evaluation was based on the safety set (SS) analysis dataset. The
359 internationally accepted MedDRA term set classification was used for adverse event
360 coding, and the types of adverse events, frequency, severity, and relationship to internal
361 brace enhancement line generation and surgery were summarized by a group. A detailed
362 list of the various adverse events is provided, with special notation for subjects who
363 discontinued the trial because of adverse events and for those who experienced serious
364 adverse events. The proportion of patients who developed complications between
365 treatments was compared using a chi-square test.

366 **Patient and public involvement**

367 Patients and/or the public were not involved in this research's design, conduct, reporting,
368 or dissemination plans.

369 **Discussion**

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3 370 This trial was conducted as a prospective randomised controlled trial to investigate the
4 371 clinical efficacy of ACLR with or without the internal brace technique. In this 2-year
5 372 follow-up study, the subjective, objective, and functional outcomes of patients who
6 373 underwent ACLR with the application of the internal brace technique or ACLR alone
7 374 were compared. This study hypothesises that ACLR with the internal brace technique
8 375 will be more stable than ACLR alone in the early postoperative period, with a lower
9 376 incidence of secondary injury, reduced duration and extent of pain, and an earlier return
10 377 to preinjury activity levels. However, there may be no significant difference between
11 378 the two groups regarding patient-reported outcome indicators as recovery time
12 379 increases.

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15 380 ACL rupture is a common knee injury in the athletic population and has been
16 381 extensively studied. Studies as early as the late 20th century have shown that ACLR is
17 382 superior to ACL repair^{32 33}. The ACL is an important structure for maintaining knee
18 383 stability, preventing anterior tibial displacement and limiting intratibial rotation³⁴,
19 384 making ACLR surgery the gold standard of treatment for patients recovering motion or
20 385 performing rotational activities after an ACL rupture in the knee³⁵. The recovery of
21 386 knee function after surgery depends on the ability of the ACL graft to withstand
22 387 appropriate loads during rehabilitation and after return to sports. The tendon graft
23 388 implanted in the human knee joint survives in the intra-articular environment and
24 389 gradually in the ligaments. The graft is fragile and vulnerable to reinjury during the pre-
25 390 remodelling phase prior to ligamentization³⁶, so a careful rehabilitation program should
26 391 be developed to prevent reinjury during the rehabilitation period. Several studies have
27 392 found a higher probability of re-rupture or secondary revision for athletes and
28 393 adolescents or for ACLR using either autologous tendons or allogeneic tendons^{10 37}.
29 394 Therefore, a surgical approach that increases the structural strength of the graft and
30 395 protects it during the early stages of graft ligamentization is of great importance.

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34 396 The biomechanical properties of the intra-articular reconstructed ligaments improved
35 397 at 8 weeks postoperatively for the FiberTape suture applied in a rabbit model.
36 398 Additionally, during this period, FiberTape did not adversely affect bone tunnel healing
37 399 or cause a long-term increase in indicators of inflammation¹². In a dog model, no severe
38 400 inflammation or immune response, bone erosion, or premature OA development was
39 401 observed 6 months postoperatively³⁸. The results of these studies will support the
40 402 biocompatibility and safety of intra-articular suture tape for ACLR enhancement.

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43 403 A study of load sharing after ACL graft enhancement by suture tape reported that load
44 404 sharing began at 200 N and 300 N for 7-mm and 9-mm grafts, respectively. The final
45 405 peak load (400 N) would be shared by 31% (7-mm graft) and 20% (9-mm graft) by the
46 406 suture tape³⁹. Suture tape ligament augmentation may protect biological grafts from
47 407 excessive peak loading and elongation. After ACLR in the early recovery phase, suture
48 408 band augmentation increases ACL graft stiffness by 104% and the ultimate breaking
49 409 load by 57%, reducing the graft failure rate in clinical situations.

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52 410 A recent systematic review paper by Christopher et al. concluded from biomechanical,
53 411 animal and clinical studies that applying suture tape augmentation in ACLR increases
54 412 biomechanical stability⁴⁰. Therefore, in this randomized controlled trial, we will
55 413 conduct a prospective observational comparison and a long-term follow-up to elucidate
56 414 the clinical efficacy of internal bracing in ACLR.

57 58 415 **Abbreviations**

- 1
2
3 416 Anterior cruciate ligament (ACL)
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5 417 Anterior cruciate ligament reconstruction (ACLR)
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7 418 International Knee Documentation Committee (IKDC)
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9 419 the Knee Injury and Osteoarthritis Outcome Score (KOOS)
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11 420 Lysholm knee score (LKS)
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13 421 Visual Analog Scale (VAS)
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15 422 ultrahigh molecular weight polyethylene (UHMWPE)
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17 423 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)
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19 424 activities of daily living (ADL)
20
21 425 sport and recreation (Sport/Rec)
22
23 426 quality of life (QOL)
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25 427 medial collateral ligament (MCL)
26
27 428 minimum clinically important difference (MCID)
28
29 429 electronic Case Report Form (eCRF)
30
31 430 safety set (SS)

431 **Ethics and dissemination**

432 The trial was approved by the Medical Ethics Committee of Xiangya Hospital of
433 Central South University on October 26, 2021, with the ethics number "202110478"
434 and prospectively registered in the China Clinical Trials Registry on March 14, 2022,
435 with the registration number: ChiCTR2200057526. All subjects signed an informed
436 consent form before participating in this trial, and we will protect the patients from any
437 invasion of their private privacy. All investigators will keep the study results
438 confidential until after the data are made public, and the investigators will release no
439 data related to the database without the approval of the principal investigator. We will
440 publish the findings and data in peer-reviewed journals and present them at national
441 and international conferences.

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447 greatly to revising the manuscript and embellishing the language.

448 **Author contributions**

449 WF-X and YS-L established the study design; WH-L conceived the design and wrote
450 the draft manuscript; D-L, ZJ-C, and LY-P were involved in data acquisition, analysis,
451 and interpretation; and WQ-X, HF-J, and X-L designed the rehabilitation protocol. All
452 authors read and approved the final manuscript.

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459 **Competing interests**

460 The authors declare that they have no competing interests regarding the present study.

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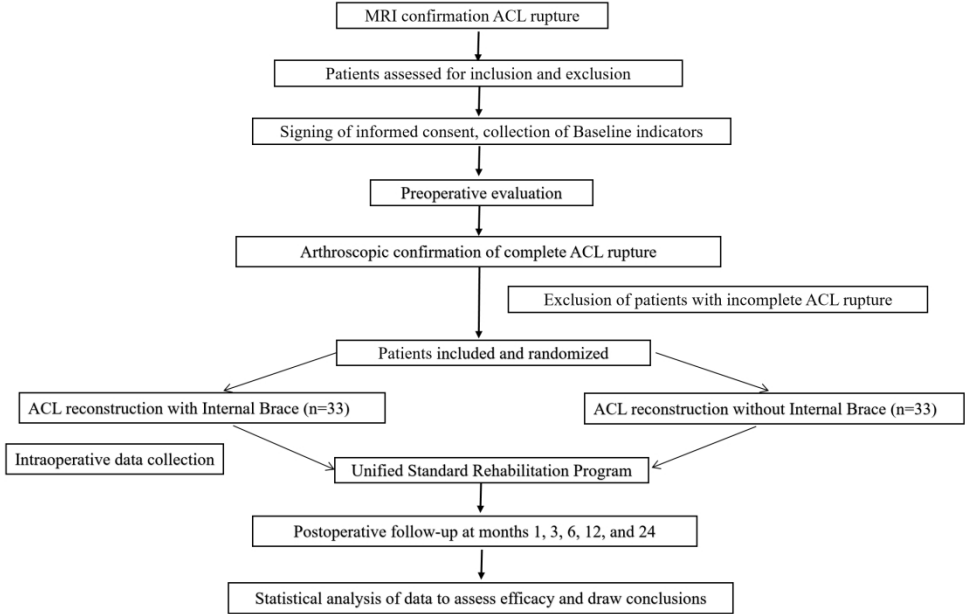
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31 639 **Fig.1** Study Flow Diagram.

33 640

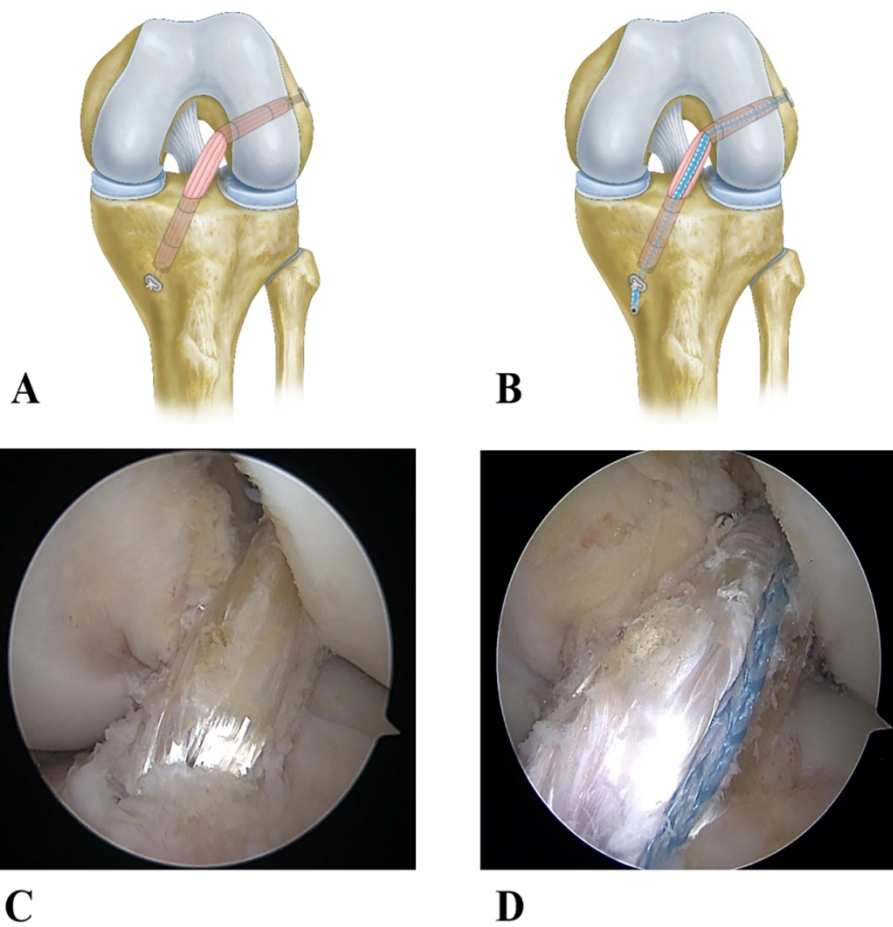
35 641 **Fig.2** A and B are the models of the control group and test group, respectively. C and
36 642 D are the pictures of the control group and test group after intraoperative arthroscopic
37 643 ACLR, respectively.

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Study Flow Diagram.

731x467mm (76 x 76 DPI)



A and B are the models of the control group and test group, respectively. C and D are the pictures of the control group and test group after intraoperative arthroscopic ACLR, respectively.

253x253mm (138 x 138 DPI)

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. *BMJ*. 2013;346:e7586

			Page
		Reporting Item	Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered,	2

1		name of intended registry	
2			
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4	Trial registration:	#2b All items from the World Health Organization Trial	2
5			
6	data set	Registration Data Set	
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9	Protocol version	#3 Date and version identifier	4
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11			
12	Funding	#4 Sources and types of financial, material, and other	11
13		support	
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17	Roles and	#5a Names, affiliations, and roles of protocol contributors	1
18			
19	responsibilities:		
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21	contributorship		
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25	Roles and	#5b Name and contact information for the trial sponsor	11
26			
27	responsibilities:		
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29	sponsor contact		
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31	information		
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34			
35	Roles and	#5c Role of study sponsor and funders, if any, in study design;	11
36		collection, management, analysis, and interpretation of	
37	responsibilities:	data; writing of the report; and the decision to submit the	
38		report for publication, including whether they will have	
39	sponsor and funder	ultimate authority over any of these activities	
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47	Roles and	#5d Composition, roles, and responsibilities of the	11
48		coordinating centre, steering committee, endpoint	
49	responsibilities:	adjudication committee, data management team, and	
50		other individuals or groups overseeing the trial, if	
51	committees	applicable (see Item 21a for data monitoring committee)	
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1 **Introduction**
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4 **Background and** [#6a](#) Description of research question and justification for 3
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6 rationale
7 undertaking the trial, including summary of relevant
8 studies (published and unpublished) examining benefits
9 and harms for each intervention
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14 **Background and** [#6b](#) Explanation for choice of comparators 3
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16 rationale: choice of
17 comparators
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22 **Objectives** [#7](#) Specific objectives or hypotheses 3
23
24

25 **Trial design** [#8](#) Description of trial design including type of trial (eg, 2
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27 parallel group, crossover, factorial, single group),
28 allocation ratio, and framework (eg, superiority,
29 equivalence, non-inferiority, exploratory)
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35 **Methods:**
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37 **Participants,**
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39 **interventions, and**
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41 **outcomes**
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45 **Study setting** [#9](#) Description of study settings (eg, community clinic, 4
46
47 academic hospital) and list of countries where data will be
48 collected. Reference to where list of study sites can be
49 obtained
50
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54 **Eligibility criteria** [#10](#) Inclusion and exclusion criteria for participants. If 4
55
56 applicable, eligibility criteria for study centres and
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1		individuals who will perform the interventions (eg,	
2		surgeons, psychotherapists)	
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5			
6	Interventions:	#11a Interventions for each group with sufficient detail to allow	5-6
7			
8	description	replication, including how and when they will be	
9			
10		administered	
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12			
13	Interventions:	#11b Criteria for discontinuing or modifying allocated	5-6
14			
15	modifications	interventions for a given trial participant (eg, drug dose	
16		change in response to harms, participant request, or	
17		improving / worsening disease)	
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22			
23	Interventions:	#11c Strategies to improve adherence to intervention protocols,	5-6
24			
25	adherence	and any procedures for monitoring adherence (eg, drug	
26		tablet return; laboratory tests)	
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31	Interventions:	#11d Relevant concomitant care and interventions that are	5-6
32			
33	concomitant care	permitted or prohibited during the trial	
34			
35			
36	Outcomes	#12 Primary, secondary, and other outcomes, including the	6-7
37			
38		specific measurement variable (eg, systolic blood	
39		pressure), analysis metric (eg, change from baseline, final	
40		value, time to event), method of aggregation (eg, median,	
41		proportion), and time point for each outcome. Explanation	
42		of the clinical relevance of chosen efficacy and harm	
43		outcomes is strongly recommended	
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53	Participant timeline	#13 Time schedule of enrolment, interventions (including any	6-7
54			
55		run-ins and washouts), assessments, and visits for	
56			
57		participants. A schematic diagram is highly recommended	
58			
59			
60			

(see Figure)

1			
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4	Sample size	#14	Estimated number of participants needed to achieve 4
5			
6			study objectives and how it was determined, including
7			
8			clinical and statistical assumptions supporting any sample
9			
10			size calculations
11			
12			
13	Recruitment	#15	Strategies for achieving adequate participant enrolment to 4
14			
15			
16			reach target sample size
17			
18			
19	Methods:		
20			
21	Assignment of		
22			
23	interventions (for		
24			
25	controlled trials)		
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29	Allocation: sequence	#16a	Method of generating the allocation sequence (eg, 4-5
30	generation		computer-generated random numbers), and list of any
31			
32			factors for stratification. To reduce predictability of a
33			
34			random sequence, details of any planned restriction (eg,
35			
36			blocking) should be provided in a separate document that
37			
38			is unavailable to those who enrol participants or assign
39			
40			interventions
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45	Allocation	#16b	Mechanism of implementing the allocation sequence (eg, 4-5
46	concealment		central telephone; sequentially numbered, opaque, sealed
47			
48	mechanism		envelopes), describing any steps to conceal the sequence
49			
50			until interventions are assigned
51			
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54			
55	Allocation:	#16c	Who will generate the allocation sequence, who will enrol 4-5
56	implementation		participants, and who will assign participants to
57			
58			
59			
60			

1		interventions	
2			
3			
4	Blinding (masking)	#17a Who will be blinded after assignment to interventions (eg,	4-5
5		trial participants, care providers, outcome assessors, data	
6		analysts), and how	
7			
8			
9			
10			
11	Blinding (masking):	#17b If blinded, circumstances under which unblinding is	4-5
12		emergency	
13		permissible, and procedure for revealing a participant's	
14	unblinding	allocated intervention during the trial	
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19	Methods: Data		
20			
21	collection,		
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23	management, and		
24			
25	analysis		
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28			
29	Data collection plan	#18a Plans for assessment and collection of outcome,	7
30		baseline, and other trial data, including any related	
31		processes to promote data quality (eg, duplicate	
32		measurements, training of assessors) and a description of	
33		study instruments (eg, questionnaires, laboratory tests)	
34		along with their reliability and validity, if known. Reference	
35		to where data collection forms can be found, if not in the	
36		protocol	
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48	Data collection plan:	#18b Plans to promote participant retention and complete	7
49	retention	follow-up, including list of any outcome data to be	
50		collected for participants who discontinue or deviate from	
51		intervention protocols	
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58	Data management	#19 Plans for data entry, coding, security, and storage,	7
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including any related processes to promote data quality
(eg, double data entry; range checks for data values).

Reference to where details of data management
procedures can be found, if not in the protocol

10 Statistics: outcomes [#20a](#) Statistical methods for analysing primary and secondary 8-9

11 outcomes. Reference to where other details of the
12 statistical analysis plan can be found, if not in the protocol

18 Statistics: additional [#20b](#) Methods for any additional analyses (eg, subgroup and 8-9
19 analyses adjusted analyses)

23 Statistics: analysis [#20c](#) Definition of analysis population relating to protocol non- 8-9

24 population and adherence (eg, as randomised analysis), and any
25 missing data statistical methods to handle missing data (eg, multiple
26 imputation)

33 Methods: Monitoring

36 Data monitoring: [#21a](#) Composition of data monitoring committee (DMC); 7

37 formal committee summary of its role and reporting structure; statement of
38 whether it is independent from the sponsor and
39 competing interests; and reference to where further
40 details about its charter can be found, if not in the
41 protocol. Alternatively, an explanation of why a DMC is
42 not needed

53 Data monitoring: [#21b](#) Description of any interim analyses and stopping 7

54 interim analysis guidelines, including who will have access to these
55 interim results and make the final decision to terminate

1		the trial	
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3			
4	Harms	#22 Plans for collecting, assessing, reporting, and managing	7
5		solicited and spontaneously reported adverse events and	
6		other unintended effects of trial interventions or trial	
7		conduct	
8			
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13	Auditing	#23 Frequency and procedures for auditing trial conduct, if	7
14		any, and whether the process will be independent from	
15		investigators and the sponsor	
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21	Ethics and		
22			
23	dissemination		
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26	Research ethics	#24 Plans for seeking research ethics committee / institutional	10
27		review board (REC / IRB) approval	
28	approval		
29			
30			
31	Protocol	#25 Plans for communicating important protocol modifications	10
32		(eg, changes to eligibility criteria, outcomes, analyses) to	
33	amendments	relevant parties (eg, investigators, REC / IRBs, trial	
34		participants, trial registries, journals, regulators)	
35			
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41	Consent or assent	#26a Who will obtain informed consent or assent from potential	10
42		trial participants or authorised surrogates, and how (see	
43		Item 32)	
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49	Consent or assent:	#26b Additional consent provisions for collection and use of	Not
50		participant data and biological specimens in ancillary	
51	ancillary studies	studies, if applicable	applicable
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57	Confidentiality	#27 How personal information about potential and enrolled	7
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1 participants will be collected, shared, and maintained in
 2 order to protect confidentiality before, during, and after
 3 the trial
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8 Declaration of [#28](#) Financial and other competing interests for principal 11
 9 interests investigators for the overall trial and each study site
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13 Data access [#29](#) Statement of who will have access to the final trial 10
 14 dataset, and disclosure of contractual agreements that
 15 limit such access for investigators
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21 Ancillary and post [#30](#) Provisions, if any, for ancillary and post-trial care, and for 7
 22 trial care compensation to those who suffer harm from trial
 23 participation
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28 Dissemination policy: [#31a](#) Plans for investigators and sponsor to communicate trial 10
 29 trial results results to participants, healthcare professionals, the
 30 public, and other relevant groups (eg, via publication,
 31 reporting in results databases, or other data sharing
 32 arrangements), including any publication restrictions
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41 Dissemination policy: [#31b](#) Authorship eligibility guidelines and any intended use of 10
 42 authorship professional writers
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46 Dissemination policy: [#31c](#) Plans, if any, for granting public access to the full 10
 47 reproducible protocol, participant-level dataset, and statistical code
 48 research
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54 Appendices

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 57 Informed consent [#32](#) Model consent form and other related documentation 10
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1 materials given to participants and authorised surrogates
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4 Biological specimens [#33](#) Plans for collection, laboratory evaluation, and storage of Not
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6 biological specimens for genetic or molecular analysis in applicable
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8 the current trial and for future use in ancillary studies, if
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Internal brace augmentation reconstruction versus standard anterior cruciate ligament reconstruction : A randomized controlled clinical trial study protocol

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4 **1 Internal brace augmentation reconstruction versus**
5 **2 standard anterior cruciate ligament reconstruction :**
6 **3 A randomized controlled clinical trial study protocol**
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12 5 Wenhao Lu^{1,2}, Di Liu^{1,2}, Zijun Cai^{1,2}, Linyuan Pan^{1,2}, Wenqing Xie^{1,2}, Hongfu Jin^{1,2},
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Abstract:

Introduction: Anterior cruciate ligament (ACL) rupture is one of the most common knee injuries in sports, and the gold standard for treating ACL rupture is tendon graft reconstruction. Internal brace technology is being used nowadays for ligament repair; however, more relevant *in vivo* clinical evidence is required for using internal brace technology in ACL reconstruction (ACLR). We conducted a randomized controlled trial to investigate the clinical efficacy of internal brace technology in ACLR.

Methods and analysis: This randomized, parallel-controlled trial included patients with ACL rupture who underwent inpatient surgery at the Department of Orthopedics, Xiangya Hospital, Central South University. Random number table method was used to assign the participants to either the test or the control group. The test group underwent ACLR using the internal brace technique, whereas the control group underwent standard ACLR. Uniform postoperative rehabilitation protocol was used for both the groups. Patient-reported outcomes included preoperative baseline and postoperative recovery at 1, 3, 6, 12, and 24 months. The primary outcome was International Knee Documentation Committee (IKDC) function from baseline (ACL rupture) to six-months postoperatively. Secondary outcomes included (I) other patient outcome reporting metrics, Lysholm knee score (LKS), Knee Injury and Osteoarthritis Outcome Score (KOOS), and Visual Analog Scale (VAS); (II) the use of Kneelax3 knee stabilizer to assess knee stability; (III) occurrence of adverse events, such as graft refraction or symptomatic instability, postoperative infection, and contralateral injury; and (IV) magnetic resonance images at 12 and 24 months after ACLR.

Ethics and dissemination: This trial was approved by the Medical Ethics Committee of the Xiangya Hospital of Central South University on October 26, 2021. Data will be published in peer-reviewed journals and presented at national and international conferences.

Trial registration number: ChiCTR2200057526.

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4 44 **Strengths and limitations of this study:**

5
6 45 This study aims to demonstrate the clinical superiority of internal braces over
7 46 conventional ACL reconstruction (ACLR) over a 2-year follow-up period.

8
9 47 This study will fill an existing gap regarding the efficacy of internal braces in ACLR
10 48 by providing robust and high-quality evidence of its role and impact.

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12 49 This study used a standard and detailed rehabilitation program to ensure smooth
13 50 recovery after ACLR.

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15 51 The single-center design of the trial will result in data to lack generalizability.

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53 Introduction

54 Anterior cruciate ligament (ACL) rupture is one of the most common knee ligament
55 injuries occurring in young athletes. Mayo-Robson of Leeds performed the first ACL
56 repair in 1895, which was followed by initiation of ACL reconstruction (ACLR) using
57 autologous tissue by Grekow and Hey Groves between 1914-1920.[1] If ACL ruptures
58 are not actively treated after injury, joint instability and other phenomena often occur,
59 which reduces the quality of life and increases the risk of osteoarthritis.[2-4] Over the
60 past few decades, ACL ruptures have been estimated to occur in approximately 30–52
61 cases per 100,000 person-years.[5] ACL injuries reportedly occur in more than 175,000
62 people annually in the United States, and approximately 100,000 undergo surgery.[6-
63 8] With the continuous development of surgical techniques, the current mainstream
64 surgical method involves performing ACLR under arthroscopy.[9] A Japanese study
65 reported that the re-disruption rate of ACLR grafts after returning to the field was 23%
66 for rugby players under the age of 20 years.[10] At the same time, other studies have
67 also shown that the revision rate of ACLR with an allogeneic tendon in adolescents can
68 reach 35%;[11] however, the effect after revision is not as good as that of primary
69 ACLR.[12]

70 Internal brace technology for ligament repair has been promoted since 2010. It uses
71 braided ultrahigh molecular weight polyethylene (UHMWPE) polyester suture tape and
72 knotless bone anchors to reinforce ligament strength, also known as an auxiliary
73 stabilizing structure for recovery of motion after ligament repair, which helps prevent
74 secondary damage,[13] such as anterior and posterior cruciate ligament, medial and
75 lateral collateral ligament repair of the knee,[13-15] and ankle and elbow ligament
76 strengthening repair.[16, 17] Enhanced collateral ligament repair and reconstruction
77 with an internal brace improves limb biomechanics, including greater stiffness and
78 maximum load, while facilitating early rehabilitation in motor and biomechanical
79 environments.[12, 14] Reinforced ligament repair offers unique advantages over
80 traditional reconstruction techniques, including smaller bores and implants, no risk of
81 disease transmission from the allografts, and no risk of tunnel convergence during the
82 procedure. [14, 18, 19] Therefore, ACL reinforcement is an alternative method for
83 synergistically supporting ACL grafts and load-sharing, with primary tension on the
84 graft and high-strength suture tape.

85 In ACLR, the internal brace ligament augmentation technique helps prevent various
86 failure scenarios, including creep and irreversible stretching, traumatic tears, and
87 slippage of the tendon-bone interface.[20, 21] In addition, these failures can be avoided
88 when the graft is small or vulnerable.[20, 21] Smith in an *in vitro* trial conducted in
89 2018 found that ACLR combined with independent suture tape significantly reduced
90 graft elongation and allowed the grafted ligaments to accept higher ultimate disruption
91 loads, thereby reducing the risk of graft rerupture.[20] Preliminary short-term studies
92 have shown that the internal brace technique can significantly improve functional
93 recovery after ACLR, thereby enhancing the patient's quality of life. However, only a
94 few medical institutions use ACLR combined with internal brace technique, and more
95 relevant *in vivo* clinical evidence is required.

96 This study was undertaken with an aim to fill this gap by exploring whether internal
97 brace technology can improve the outcomes of patients with ligament injuries and
98 provide a new option for patients with ACL injuries.

99 **Methods and analysis**

100 **Study setting**

101 This randomized parallel-controlled trial will be conducted in accordance with the
102 CONSORT statement.[22] Patients with ACL rupture who were hospitalized in the
103 Department of Orthopedics at Xiangya Hospital of Central South University between
104 March 1, 2022 and February 28, 2023 formed our study population. The Medical Ethics
105 Committee of Xiangya Hospital of Central South University approved the ethical
106 application related to this study and filed it (ethical approval number: 202110478). All
107 patients signed an informed consent form prior to the surgery.

108 **Eligibility criteria**

109 The inclusion criteria were: (1) age: 16-45 years; (2) unilateral knee magnetic resonance
110 imaging (MRI) showing unilateral knee ACL fracture; (3) combined meniscal injury
111 that does not interfere with the standard postoperative rehabilitation program after
112 intraoperative management; (4) combined grade III or lower cartilage injury that does
113 not interfere with the standard postoperative rehabilitation program; (5) a minimum of
114 24 months of follow-up; (6) no previous injury to the healthy knee; (7) informed
115 consent provided by the participant and signed relevant documents.

116 The exclusion criteria were: (1) age of <16 years or >45 years; (2) previous ACLR or
117 bilateral ACL injury; (3) MRI revealing posterior cruciate ligament (PCL), medial
118 collateral ligament (MCL), or lateral collateral ligament (LCL) injury; (4) grade IV
119 cartilage injury or unstable longitudinal meniscus tear requiring repair that interferes
120 with standard rehabilitation protocols after surgical management; (5) not meeting the
121 requirement of 24 follow-up visits; (6) patients with severe underlying medical
122 conditions that make surgery inadvisable, or patients with mental illness, pregnancy
123 during planned trials, or other conditions that are not conducive for long-term follow-
124 up.

125 **Participant selection:**

126 Patients diagnosed with ACL rupture by clinicians through physical examination and
127 MRI were randomly allocated to the trial and control groups after final confirmation of
128 ACL rupture under arthroscopy and agreeing to participate in this study. The trial group
129 underwent ACLR with the internal brace technique, while the control group underwent
130 ACLR without the internal brace technique. Preoperative assessment of the patients
131 was performed before surgery, and a uniform rehabilitation program was performed
132 after surgery. The inclusion start date of the protocol (version 1.0, March 2022) was
133 March 2022, with an expected cutoff date of March 2023. The follow-up period is 2
134 years, with the last follow-up expected in March 2025 (the exact end date will be based
135 on the inclusion of the last participant). The specific technical route is shown in **Fig. 1**.

136 **Study sample**

137 International Knee Documentation Committee (IKDC) score consists of three aspects:
138 1) symptoms, including pain, stiffness, swelling, interlocking/jamming, and softening
139 of the legs; 2) motion and daily activities; and 3) current knee function. However, knee
140 function prior to knee injury does not count towards the total score, which is the main
141 outcome indicator of this study, based on which the sample size required for this trial
142 was estimated. IKDC scores are continuous measurement data, and this study compares

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3 143 the statistical differences between the means \pm standard deviations of the two groups.
4 144 The minimum clinically important difference (MCID) of the IKDC scale was reported
5 145 to range between 8.8-15.6.[23-25] We set δ to 10, and the overall sample standard
6 146 deviation was set to 13 based on the relevant literature.[23-25] To satisfy the power of
7 147 a test ($1-\beta$, β means type II error) of 0.8 and the test level α (type I error) of 0.05, the
8 148 sample size calculated for each group was 27 according to the following formula.
9 149 Considering a 20% lost visit rate, 33 patients were included in each group with a total
10 150 of 66 patients included in the study.

151 **Randomization and Concealed Grouping**

152 Using a computer-generated random number list, all eligible participants were
153 randomly assigned in a 1:1 ratio to the ACLR endoprosthesis technique group
154 (combined group, n=33) and the standard ACLR group (simple group, n=33), with no
155 restrictions on either group. Randomization was performed by an investigator who was
156 not involved in the study. Allocation results were sealed in opaque envelopes and
157 maintained by the study coordinator. On the day of surgery, one envelope per patient
158 was given to the surgeon by the study coordinator. The participants and physicians
159 included in the study were informed of the grouping, but neither the rehabilitators who
160 instructed the patients on rehabilitation nor the data collectors who conducted the
161 follow-up visits were aware of the grouping.

162 **Interventions and surgical techniques**

163 In all patients, all-inside ACLR was performed using autologous semitendinosus
164 tendons with arthroscopy. Semitendinosus tendons were braided with sutures (0
165 FiberWire Suture, Arthrex) to form four strands of ACL grafts (all between 7.5-10 mm
166 in diameter, supplemented with semimembranous tendons less than 7.5 mm in
167 diameter). In the ACLR group, the braided graft femoral end and tibial segment were
168 suspended and fixed with a TightRope (ACL TightRope RT Implant, Arthrex). On the
169 other hand, in the ACLR with internal brace group, a separate wire tape (2 mm
170 FiberTape, Arthrex) was added in addition to the components and technique used in the
171 ACLR group. The suture was fixed with a knotless bone anchor (4.75-mm PEEK
172 SwiveLock, Arthrex) distally and a TightRope suspension proximally as in the graft
173 (Fig. 2).

174 The procedure was as follows: the patient was anesthetized, a tourniquet was applied
175 to the affected limb, routine surgical disinfection of the knee was performed, a sterile
176 surgical sheet was placed, the semitendinosus tendon was palpated, a straight incision
177 was made medial to the tibial tuberosity, the semitendinosus tendon was removed with
178 a tendon extractor, 10 ml of ropivacaine was injected at the tendon extraction site, and
179 the removed semitendinosus tendon was braided into four strands using the GraftLink
180 (Arthrex) technique.[26] A conventional knee arthroscopic approach was used on the
181 anteromedial and anterolateral sides of the affected knee to explore the injured
182 structures and remove the remaining portion of the ACL. The knee was flexed to the
183 extreme, and the femoral tract was created at the footprint of the ACL stop at the lateral
184 femoral condyle and the tibial tract at the footprint of the ACL start. The graft and two
185 TightRope titanium plates were pulled into the knee cavity and removed through the
186 femoral and tibial tracts, respectively. The tabs were flipped, the tab rings were
187 tightened, and the titanium plates were fixed. In the ACLR with an internal brace group,
188 the femoral end of the FiberTape wire band was fixed with a TightRope ring, the wire
189 band was tensioned in the extended position, and the tibial end was fixed independently

190 with a knotless bone anchor (4.75-mm PEEK SwiveLock, Arthrex).

191 All patients underwent uniform training and rehabilitation program after surgery. The
 192 entire rehabilitation process was divided into seven phases. The first three phases
 193 focused on controlling swelling and restoring the range of motion, which usually
 194 required four weeks. The detailed rehabilitation plan is presented in **Table 1**. Phases
 195 4-5 focused on restoring quadriceps muscle strength control and balance along with
 196 core strength restoration training. Phases 6-7 included gradual resumption of various
 197 sports activities, from daily activities to professional activities or contact sports. A
 198 detailed rehabilitation plan has been presented in **Tables 2** and **3**.

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Table 1. Phases 1-3 of the post-ACLR rehabilitation program

Phase	Movement Exercises	Gait Exercises	Manipulative Massage	Rehabilitation Goals	Precautions
Phase 1 (within 1 week)	(1) Placing the heel against the bed for flexion and extension sliding; supine position, the affected leg bends the hip, flexes the knee and places the heel on the wall for flexion and extension sliding; sitting position, legs on the floor; the healthy leg is placed in front of the affected leg and assists the affected leg in flexing the knee. (2) Ankle pump exercises (the affected leg is elevated, and the foot performs upward hooking and downward stepping movements, along with rotational movements). (3) Anterior thigh muscle tensing exercises with the knee in straight position (can be combined with neuromuscular electrical stimulation or biofeedback exercises). (4) Hip muscle group training. (5) Pillow clamping of the legs for medial thigh muscle group strength training. (6) The brace is locked in 0° position, and the affected leg is lifted in the supine and prone positions for muscle strength training. (7) Passive knee extension exercises: prone position with the affected knee extended out of bed for suspension or supine position with the affected leg in a slightly elevated heel position and the knee joint suspended. (8) Weight transfer training (front-to-back and left-to-right) can be performed in the above mentioned weight-bearing exercise position. (9) Continuous passive movement apparatus training with increased knee flexion by 5° to 10°/day.	(1) Flat and step gait training with the support of a knee protection brace and double crutches. (2) Cold compresses after training to reduce edema.	(1) Pushing the patella in all directions. (2) Manipulation of the posterior thigh muscles of the affected limb or sitting and standing to pull the muscles to relieve their spasm.	Active mobility of the knee joint reaches 0°- 90°. (1) The anterolateral thigh muscles can be tightened better. (2) The affected limb can be fully weight-bearing with the help of braces and crutches. (3) Edema control is good. (4) Good wound healing.	(1) Brace locked in 0° position, crutches, and weight-bearing exercises within a tolerable range. (2) Wearing the brace at night and locking it in 0° position while sleeping with the affected leg elevated.
Phase 2 (1-2 weeks)	(1) Fixed cycling exercises (from small to a full range of pedal rotation). (2) Tightening and 90° muscle strength exercises for anterior thigh muscles in straight position. (3) Standing balance training on the affected leg with a single leg wearing support. (4) Balance training on a balance board with forward and backward weight transfer. (5) Continuous passive activity equipment training. (6) Starting small partial weight-bearing squat exercises (within 30° of knee flexion). (7) Passive straightening exercises with the heel slightly elevated and the knee hanging in air. (8) Straight leg raises training (all directions). (9) Terminal angle knee extension training in the standing position using an elastic band.	(1) The healthy leg stands outside the treadmill with weight, and the affected leg simulates walking on the treadmill. (2) The affected leg crosses the	(1) Manipulation to push the patella treatment. (2) Manipulation of the posterior thigh muscle group for relaxation and stretching exercises.	Active mobility of the knee joint reaches 0°-120°. (1) Straight leg elevation; anterior thigh muscles can be tightened with force. (2) The patient can walk normally using crutches with a nonlocking brace.	(1) Weight-bearing exercises within tolerable limits. (2) Transition from double to single crutch. (3) When the strength of the anterior thigh muscle group is well exercised, the locking brace can be gradually dispensed (the anterior thigh muscle group can be unlocked to more than 30° only when it can

		obstacle training and simulates walking.		contract forcefully to keep the straight leg elevated).
Phase 3 (2-4 weeks)	(1) Fixed bicycle training gradually increases the resistance to improve exercise endurance. (2) Tightening exercises for the anterior thigh muscle group in straight position and muscle strength exercises in the range of 60°-90° until the muscle strength of both legs is equal. (3) 0°-60° squat training, gradually increasing the resistance strength (for patients with meniscal repair, squat to the target angle on the healthy leg before shifting the weight to the middle of the two legs). (4) Stand with both legs on a balance board for balance training in multiple directions. (5) Single-leg standing balance training on the affected leg (with eyes closed and open and on a support surface with different degrees of softness). (6) Straight leg raise training in the standing position can increase resistance appropriately.	Exercise with a rope tied around the waist or on a treadmill for forward and backward gait training.	(1) Manipulation to push the patella treatment. (2) Manipulation of the surgical scar. (3) Manipulative passive knee flexion or extension angle exercises.	The knee joint moves to an active full angle, aligning with the healthy side leg. (1) Normal gait can be achieved without any walking aid. (2) Self-care in daily life (may have difficulty walking up and down steps).
				Fully weight bearing; normal gait can be achieved without a brace or walker at three weeks postoperatively.

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Table 2: Phases 4-5 of the post-ACLR rehabilitation program

Phase	Movement Exercises	Gait Exercises	Manipulative Massage	Rehabilitation Goals	Precautions
Phase 4 (4-8 weeks)	(1) Fixed cycling training: gradually increasing the resistance. (2) Squat training: Transition from double leg to single leg (0°-60°), gradually increasing resistance. (3) Lunge training (0°-60°). (4) Step training: centripetal and centrifugal contraction of the anterior thigh muscles (knee does not exceed 60°). (5) Tiptoe training: Transition from double leg to single leg. (6) Swing exercise: Standing using the affected leg, and the healthy leg is strapped with an elastic band and swings, transitioning from front-to-back swing to lateral swing and then to rotation or random direction movement. (7) Rotational stability training: static lunge stance, lateral pull pulley exercise. (8) Exercise with a rope tied around the waist to provide resistance; walking exercises in forward and backward, left and right directions. (9) Walking exercises on the treadmill in four directions. (10) Balance board training: various support surfaces, double-legged standing. (11) Single-leg stand for ball tossing exercises. (12) Core training: supine or prone position for bridge exercise, standing to pull the pulley.	Go around the obstacles at normal walking speed on different surfaces.	Manual method to loosen surgical scars.	(1) Center of gravity in the middle, squatting bilaterally to 60° (no more than 60°). (2) Knee in good condition (slight pain and effusion, no instability). (3) The circumference at the upper edge of the patella is 10 cm, with a 1-2 cm difference between the legs. (4) The affected limb can maintain balance for > 30 s while standing on one leg with little body sway.	(1) No participation in sports which have a high impact on the joints, such as running or jumping. (2) No participation in sports with high lateral stress on the joints. (3) Avoid squatting deeply (limited to 0°-60°).
Phase 5 (8-12 weeks)	(1) Squat training: transition from double to single leg (0°-60°), gradually increasing resistance. (2) Lunge training (0°-60°). (3) Tiptoe training: Transition from double-leg to single-leg. (4) Increasing the strength of the posterior lateral muscle group with plyometric training. Core muscle strength training. ① Combined strength and balance training (throwing and catching balls on the balance board, and small squats on the balance board) ② Advanced balance function training (affected leg standing on one leg, hand or opposite foot to touch objects on the ground or lateral pulling elastic band) ③ Swimming training, in addition to breaststroke. Additionally, care should be taken not to stir the leg at	—	—	(1) The thigh circumference of both legs is approximately the same (within 1 cm of each other). (2) The affected limb squats to 60° on one leg. (3) The affected limb can stand on one leg to maintain balance for 60 s. (4) Little, if any, edema with activity.	Patellar tendonitis may occur.

a deep squatting angle or to use a splint when swimming.
④ Cycling training every other day.

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207 **Table 3: Phases 6-7 of the post-ACLR rehabilitation program**

208

Phase	Movement Exercises	Gait Exercises	Manipulative Massage	Rehabilitation Goals	Precautions
Phase 6 (12-16 weeks)	(1) Jogging movement: multiple directions for running. (2) Increasing the speed of all sports. (3) Skateboard training, slow walking in water and other forms of exercise can be carried out.	—	—	(1) Squat down to 60° on one leg with the affected limb and repeat 20 times. (2) The affected leg can stand on one leg to maintain balance for at least 60 s. (3) Vertical or horizontal jump using both legs with a good landing position. (4) Single-leg jump: 80% of the ability of the healthy leg is achieved.	Avoid wrong movements or posture. (1) Landing with the knee joint too straight. (2) The knee joint is turned outward or inward when landing. (3) When landing or bouncing, the healthy leg always takes the lead, not the affected leg.
Phase 6 (12-16 weeks)	(1) Progressive running program. (2) Testing and training of single-leg jumping. (3) Vertical or horizontal jumps, transitioning from double to single leg. (4) Progressive enhancement type training (box jumps, side jumps, standing jumps, deep squat jumps, etc.). (5) Speed and agility training (join professional sports training).	—	—	After 20 weeks, they participate in a professional sports program.	—

209

210 **Baseline indicators and observations**

211 Baseline and preoperative patient characteristics included sex, age, affected limb (left
212 or right), cause of injury (playing basketball or other sports such as soccer), smoking
213 status (yes or no), time from injury to surgery (fresh injury or old rupture), whether the
214 injury was accompanied by cartilage and meniscal damage, time of surgery, and degree
215 of ACL fracture (partial or total).

216

217 **Study endpoints**

218 **Primary outcome/endpoint:** IKDC score changes in knee function from preoperative
219 period to 6 months postoperatively was the primary outcome. The IKDC is a commonly
220 used tool to evaluate outcomes after knee surgery, including ACLR. [27] The IKDC
221 knee score consists of knee assessment (10 entries) and knee ligament checklist (eight
222 entries), covering joint pain, motor level, and daily activity ability, with total score
223 ranging between 0-100. The IKDC can be used to assess knee symptoms, function, and
224 physical activity. The IKDC assesses symptoms, function, and physical activity of the
225 knee. Patients were evaluated using a questionnaire preoperatively and at follow-up
226 visits at 1, 3, 6, 12, and 24 months postoperatively.

227 **Secondary outcomes/endpoints:** Lysholm knee score (LKS), Knee Injury and
228 Osteoarthritis Outcome Score (KOOS, including knee symptoms, pain, activities of
229 daily living, sports and recreational activities, and quality of life), Visual Analog Scale
230 (VAS, for pain assessment), Lachman test, MRI data, and assessment of knee stability
231 using the Kneelax3 knee stability meter.

232 (1) *Kneelax3 (MONITORED REHAB SYSTEMS B.V. Model: KNEELAX3, The*
233 *Netherlands):* The Kneelax3 arthrometer was used for assessment of knee stability
234 preoperatively and 1, 3, 6, 12, and 24 months postoperatively.

235 (2) *LKS:* This scoring system consists of eight questions scored on a scale of 0-100,
236 with higher scores representing better functional status of the patient. The main
237 tendency is toward activities of daily living, and patients were assessed using
238 questionnaires before surgery and at 1, 3, 6, 12, and 24 months of postoperative follow-
239 up visits.[28]

240 (3) *KOOS score:* The KOOS consists of five subscales: pain, other knee symptoms,
241 activities of daily living, function in sports and recreation (Sport/Rec), and knee-related
242 quality of life.[29] Patients were given one week for consideration before answering
243 the questions, and each question had five alternative boxes with scores ranging between
244 0-4. Standard scores were calculated for each subscale (100 for no symptoms and 0 for
245 extreme symptoms), and patients were assessed using questionnaires before surgery
246 and at follow-up visits at 1, 3, 6, 12, and 24 months after surgery.

247 (4) *VAS score:* The visual analogue pain scoring method is more sensitive and
248 comparable. In this trial, a 100-mm VAS pain score (including resting-state score, 30-
249 min post-walk score, and overall pain level in the past month) was used.[30] This
250 protocol only assessed pain at rest, with 0 representing no pain and 100 representing
251 the most severe pain. Patients were evaluated using questionnaires before surgery and
252 at 1, 3, 6, 12, and 24 months of postoperative follow-up.

253 (5) *Lachman test:* This assesses ACL function with the patient in supine or prone
254 position and knee flexed at an angle of approximately 30°.[31] The examiner uses one
255 hand to immobilize the thigh while the other hand attempts to move the tibia forward.
256 Positive results suggest that patients with ACL injuries be tested preoperatively and at
257 follow-up visits at 1, 3, 6, 12, and 24 months postoperatively.

258 (6) *MRI assessment:* MRI was performed at 12 and 24 months postoperatively to assess
259 the patient's reconstructed ACL.

260

261 **Patient termination and withdrawal criteria**

262 Patients could withdraw from the trial at any time due to the following reasons:

263 (1) **Surgical failure:** 1) occurrence of infection; 2) no secondary rupture of the
264 reconstructed ligament (rupture of the ligament or the internal brace augmentation line
265 or both in the trial group, rupture of the reconstructed ligament in the control group);
266 and 3) knee instability: self-reported knee instability, or Lachman test (+) or Kneelax3
267 knee arthrometer test revealing a 3-mm difference in comparison with the healthy side.

268 (2) **Patient withdrawal from the trial:** All participants had the right to withdraw at any
269 time during the study period. A participant was withdrawn from the trial if any of the

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2
3 270 following occurred during the trial: 1) withdrawal of informed consent by the
4 271 participant; 2) a person who, in the opinion of the investigator, was no longer suitable
5 272 for continuation of the clinical trial; 3) a woman who became pregnant during the
6 273 clinical trial; 4) death of the participant; or 5) the participant was lost to follow-up.

8
9 274 **(3) Trial termination:**

10 275 1) The clinical trial institution and investigator found that the risks to patients by
11 276 continuing the clinical trial exceeded the possible benefits; 2) the ethics committee
12 277 found that the rights of the participants could not be protected; 3) the sponsor requested
13 278 termination of the trial for various reasons; and 4) the national administrative authority
14 279 requested termination.

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16
17 280 The timing and reasons for withdrawal from the trial were recorded in detail in the case
18 281 report form. Follow-up care was no longer provided for participants who voluntarily
19 282 withdrew from the treatment, as well as for those for whom follow-up data were not
20 283 being collected. However, participants who withdrew from the trial due to adverse
21 284 events or because of surgical failure were to be followed up until the adverse events
22 285 stabilized or resolved or until the investigator deemed that further follow-up was no
23 286 longer necessary.

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27 288 **Data management**

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29 289 The trial used an electronic data collection (EDC) system for data management. The
30 290 investigator or investigator-authorized research staff completed the electronic Case
31 291 Report Form (eCRF) through the EDC system in an accurate, timely, complete, and
32 292 standardized manner, based on the original information from the participants.
33 293 Questionnaire checking, data cleaning, and summarization were performed promptly
34 294 after each follow-up visit. A follow-up survey is proposed to adopt the electronic
35 295 questionnaire system and on-site questionnaire survey. The on-site survey results will
36 296 be saved in time and organized in the database later. The investigator or investigator's
37 297 authorized researcher will enter the data into the EDC according to their respective
38 298 accounts. The data administrator verifies the reliability, completeness, and accuracy of
39 299 the data in the EDC. If any questionable data are found, a challenge can be issued in
40 300 the system, and the investigator or the investigator's delegated researcher will verify,
41 301 correct, or answer the query. When all the data have been entered into the database and
42 302 all queries have been resolved, the database will be locked by the data administrator. If
43 303 a problem is found after the database is locked and there is a need to correct it, the
44 304 process of unlocking and relocking the data will be followed. After the database is
45 305 locked, the data manager will submit the data to the analyst for statistical analysis as
46 306 scheduled.

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52 308 **Statistical analysis**

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54 309 **(1) Statistical design:** This was a randomized controlled clinical trial.

55
56 310 **(2) Principles of Statistical Analysis:** All statistical analyses were performed using
57 311 SAS version 9.4 or later, R version 3.3.2 or later, or SPSS24(IBM Corporate
58 312 Headquarters, Armonk, New York, USA). All statistical tests were two-sided tests, and
59 313 P values ≤ 0.05 were considered statistically significant for the differences tested

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3 314 (unless otherwise specified).
4

5 315 i) Summary statistics for continuous variables: including the mean, standard deviation,
6 316 median, minimum, maximum, lower quartile (Q1), and upper quartile (Q3); summary
7 317 statistics for categorical variables, including the number of cases and percentages of
8 318 each category.

9
10 319 ii) Between-group comparisons of demographic baseline characteristics: Group
11 320 comparisons for continuous variables will be made using independent samples t-test
12 321 (chi-square, normal distribution) or Wilcoxon rank-sum test depending on data
13 322 distribution, and chi-square test or exact probability method for categorical variables
14 323 (if chi-square test is not applicable).

15
16 324 **(3) Completion and demographic analyses:** Baseline analyses were based on full
17 325 analysis set (FAS). The enrollment and completion status of the trials were summarized
18 326 and the reasons for non-completion are described in a detailed table. The participants'
19 327 demographic characteristics were described and compared to measure comparability
20 328 between the two groups. Validity reporting data were accepted only if the baseline was
21 329 balanced between the groups; otherwise, the validity data were corrected before
22 330 reporting.

23
24 331 **(4) Patient-reported outcome validity evaluation indices:** Outcome validity evaluation
25 332 will be based on the FAS and the per-protocol set (PPS). The statistical description and
26 333 inference of the data will be based on the characteristics of the data, the selection of
27 334 applicable descriptive indicators, and hypothesis testing methods.

28
29 335 *Primary patient-reported outcome:* Comparison of IKDC knee scores at six-months
30 336 (± 2 weeks) postoperatively in the trial and control groups. We will use a linear
31 337 regression model for analysis to correct for possible confounding factors such as age,
32 338 sex, and cause of injury. Preoperative baseline IKDC scores will be used as predictors
33 339 when conducting the analysis, and IKDC scores at 6 months (± 2 weeks) will be used as
34 340 indicators of post-treatment outcomes.

35
36 341 *Secondary patient-reported outcomes*

37
38 342 i) Since IKDC scores were measured multiple times during the follow-up period, we
39 343 will use a linear mixed model to compare the changes over time between the trial and
40 344 control groups.

41
42 345 ii) The anterior tibial translation distance is measured using the Kneelax3 knee stability
43 346 meter, and comparisons of the anterior tibial translation distance between the test and
44 347 control groups at the same postoperative time points with the same force will be
45 348 performed using either an independent samples t-test (chi-square, normally distributed)
46 349 or a Wilcoxon rank sum test. A linear mixed model will also be used to compare and
47 350 analyze the evolution of these consecutive results over time in both groups.

48
49 351 iii) A comparative analysis of failure and infection rates in the control group versus the
50 352 test group during the main six months will be performed using the chi-square test or t-
51 353 test.

52
53 354 iv) Linear regression of continuous outcomes from baseline to 24 months, such as LKS,
54 355 KOOS score (including knee symptoms, pain, activities of daily living, sports and
55 356 recreational activities, quality of life), Lachman test, and pain VAS protocols, will be
56 357 used to compare and analyze the evolution of these continuous outcomes over time in

1
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3 358 the two groups using linear mixed models.
4

5 359 v) The morphology and signal intensity of the postoperative ACL will be assessed using
6 360 MRI, and different treatments will be compared at different time points using chi-square
7 361 test.
8

9 362

10 363 **Analysis of safety indicators**

11
12 364 Safety evaluation will be based on a safety-set (SS) analysis dataset. The internationally
13 365 accepted Medical Dictionary for Regulatory Activities (MedDRA) term set
14 366 classification was used for adverse event coding. The types of adverse events,
15 367 frequency, severity, and relationship with internal brace enhancement line generation
16 368 and surgery were summarized by group. A detailed list of the various adverse events is
17 369 provided, with special notations for participants who discontinued the trial because of
18 370 adverse events and for those who experienced serious adverse events. The proportions
19 371 of patients who developed complications between treatments were compared using the
20 372 chi-square test.
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25 374 **Patient and public involvement**

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27 375 Patients and/or the public were not involved in the study design, conduct, reporting, or
28 376 dissemination plans.
29

30 377

31 378 **Discussion**

32
33 379 This prospective, randomized controlled trial aimed to investigate the clinical efficacy
34 380 of ACLR with and without the internal brace technique. In this 2-year follow-up study,
35 381 the subjective, objective, and functional outcomes of patients who underwent ACLR
36 382 with the internal brace technique or ACLR alone were compared. This study
37 383 hypothesized that ACLR with internal brace technique would be more stable than
38 384 ACLR alone in the early postoperative period, with a lower incidence of secondary
39 385 injury, reduced duration and extent of pain, and earlier return to preinjury activity levels.
40 386 However, there may be no significant difference between the two groups in terms of
41 387 patient-reported outcome indicators with increase in recovery time.
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45 388 ACL rupture is a common knee injury among athletes and has been extensively studied.
46 389 Studies from as early as the late 20th century have shown that ACLR is superior to ACL
47 390 repair.[32, 33] The ACL is an important structure for maintaining knee stability,
48 391 preventing anterior tibial displacement, and limiting intratibial rotation,[34] making
49 392 ACLR the gold standard treatment for patients recovering motion or performing
50 393 rotational activities after ACL rupture in the knee.[35] The recovery of knee function
51 394 after surgery depends on the ability of the ACL graft to withstand appropriate loads
52 395 during rehabilitation and after returning to sports. Tendon grafts implanted in the human
53 396 knee joint survive in the intra-articular environment and gradually in the ligaments. The
54 397 graft is fragile and vulnerable to reinjury during the pre-remodeling phase before
55 398 ligamentization,[36] so a carefully designed rehabilitation program should be
56 399 developed to prevent reinjury during the rehabilitation period. Several studies have
57 400 found a higher probability of re-rupture or secondary revision in athletes and
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3 401 adolescents or for ACLR using either autologous or allogeneic tendons.[10, 37]
4 402 Therefore, a surgical approach that increases the structural strength of the graft and
5 403 protects it during the early stages of graft ligamentization is important.

7 404 The biomechanical properties of the intraarticular reconstructed ligaments reportedly
8 405 improved 8 weeks postoperatively when the FiberTape suture was applied in a rabbit
9 406 model. Additionally, during this period, FiberTape did not adversely affect bone tunnel
10 407 healing or cause a long-term increase in indicators of inflammation.[12] In a dog model,
11 408 no severe inflammation, immune response, bone erosion, or premature osteoarthritis
12 409 development was observed 6 months postoperatively.[38] The results of these studies
13 410 support the biocompatibility and safety of intraarticular suture tape for ACLR
14 411 enhancement.

17 412 A study on load sharing after ACL graft enhancement using suture tape reported that
18 413 load sharing began at 200 N and 300 N for 7-mm and 9-mm grafts, respectively. The
19 414 final peak load (400 N) was shared by 31% (7-mm graft) and 20% (9-mm graft) when
20 415 using suture tape.[39] Suture tape ligament augmentation may protect biological grafts
21 416 from excessive peak loading and elongation. After ACLR in the early recovery phase,
22 417 suture band augmentation reportedly increases ACL graft stiffness by 104% and the
23 418 ultimate breaking load by 57%, reducing the graft failure rate in clinical situations.

26 419 A recent systematic review by Christopher et al. concluded from biomechanical, animal,
27 420 and clinical studies that suture tape augmentation in ACLR increased biomechanical
28 421 stability.[40] Therefore, in this randomized controlled trial, we will conduct a
29 422 prospective observational comparison and long-term follow-up to elucidate the clinical
30 423 efficacy of internal bracing in ACLR.

32 424

34 425 **Ethics and dissemination**

36 426 The trial was approved by the Medical Ethics Committee of Xiangya Hospital of
37 427 Central South University on October 26, 2021 (ethics number "202110478") and
38 428 prospectively registered in the China Clinical Trials Registry on March 14, 2022
39 429 (registration number: ChiCTR2200057526). All participants signed an informed
40 430 consent form before participating in this trial, and we will protect the patients from any
41 431 invasion of their privacy. All investigators will keep the study results confidential until
42 432 after the data are made public and will release no data related to the database without
43 433 approval from the principal investigator. We will publish our findings and data in peer-
44 434 reviewed journals and present them at national and international conferences.

47 435 **Abbreviations**

49 436 Anterior cruciate ligament (ACL)

51 437 Anterior cruciate ligament reconstruction (ACLR)

53 438 International Knee Documentation Committee (IKDC)

54 439 the Knee Injury and Osteoarthritis Outcome Score (KOOS)

56 440 Lysholm knee score (LKS)

58 441 Visual Analog Scale (VAS)

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3 442 ultrahigh molecular weight polyethene (UHMWPE)
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5 443 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)
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7 444 activities of daily living (ADL)
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9 445 sport and recreation (Sport/Rec)
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11 446 quality of life (QOL)
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13 447 medial collateral ligament (MCL)
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15 448 minimum clinically important difference (MCID)
16
17 449 electronic Case Report Form (eCRF)
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19 450 safety set (SS)
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21 451 Medical Dictionary for Regulatory Activities (MedDRA)

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473 **Author contributions**

53 474 WF-X and YS-L established the study design; WH-L conceived the design and wrote
54 475 the draft manuscript; D-L, ZJ-C, and LY-P were involved in data acquisition, analysis,

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3 476 and interpretation; and WQ-X, HF-J, and X-L designed the rehabilitation protocol. All
4 477 the authors have read and approved the final version of the manuscript.

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484 **Competing interests**

485 The authors declare that they have no competing interests.

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555 and Osteoarthritis Outcome Score Physical Function Short Form (KOOS-PS), Knee
556 Outcome Survey Activities of Daily Living Scale (KOS-ADL), Lysholm Knee Scoring
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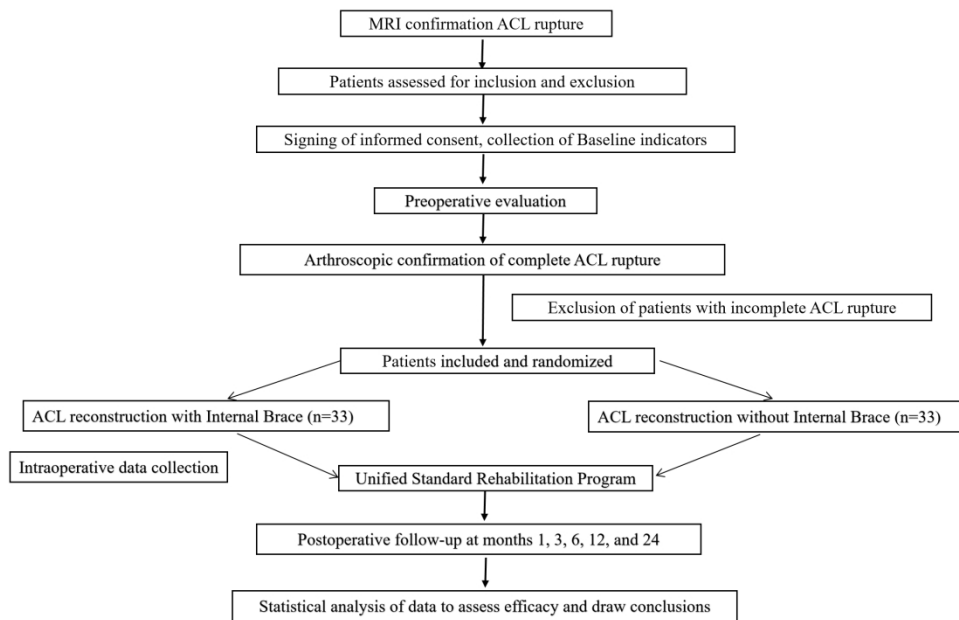
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609 **Figure legends**

610 **Fig.1** Study Flow Diagram.

611 **Fig.2** A and B are the models of control and test groups, respectively. C and D are the
612 pictures of control and test groups after intraoperative arthroscopic ACLR, respectively.

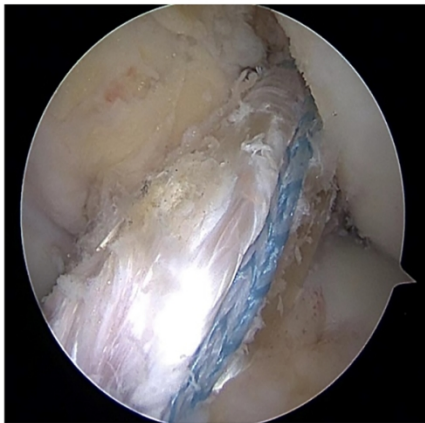
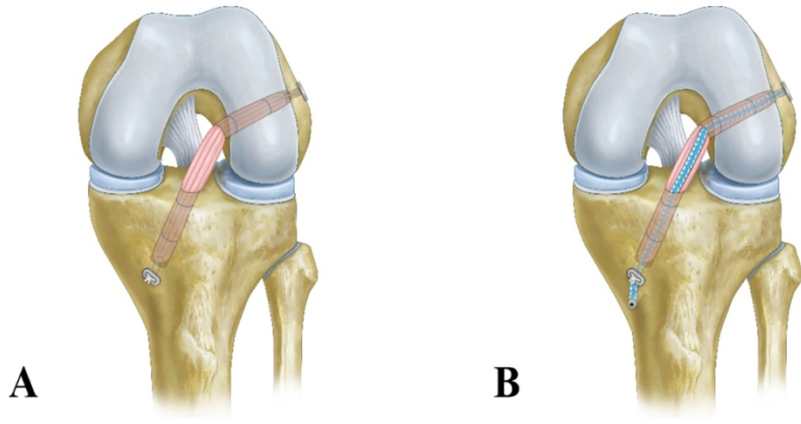
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Study Flow Diagram.

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A and B are the models of control and test groups, respectively. C and D are the pictures of control and test groups after intraoperative arthroscopic ACLR, respectively.

253x253mm (138 x 138 DPI)

Reporting checklist for protocol of a clinical trial.

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Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. *BMJ*. 2013;346:e7586

			Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered,	2

1		name of intended registry	
2			
3			
4	Trial registration:	#2b All items from the World Health Organization Trial	2
5			
6	data set	Registration Data Set	
7			
8			
9	Protocol version	#3 Date and version identifier	4
10			
11			
12	Funding	#4 Sources and types of financial, material, and other	11
13			
14		support	
15			
16			
17	Roles and	#5a Names, affiliations, and roles of protocol contributors	1
18			
19	responsibilities:		
20			
21	contributorship		
22			
23			
24			
25	Roles and	#5b Name and contact information for the trial sponsor	11
26			
27	responsibilities:		
28			
29	sponsor contact		
30			
31	information		
32			
33			
34			
35	Roles and	#5c Role of study sponsor and funders, if any, in study design;	11
36			
37	responsibilities:	collection, management, analysis, and interpretation of	
38			
39	sponsor and funder	data; writing of the report; and the decision to submit the	
40			
41		report for publication, including whether they will have	
42			
43		ultimate authority over any of these activities	
44			
45			
46			
47	Roles and	#5d Composition, roles, and responsibilities of the	11
48			
49	responsibilities:	coordinating centre, steering committee, endpoint	
50			
51	committees	adjudication committee, data management team, and	
52			
53		other individuals or groups overseeing the trial, if	
54			
55		applicable (see Item 21a for data monitoring committee)	
56			
57			
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1 **Introduction**
2

3
4 **Background and** [#6a](#) Description of research question and justification for 3
5
6 rationale undertaking the trial, including summary of relevant
7 studies (published and unpublished) examining benefits
8 and harms for each intervention
9
10
11
12

13
14 **Background and** [#6b](#) Explanation for choice of comparators 3
15
16 rationale: choice of
17 comparators
18
19
20

21 **Objectives** [#7](#) Specific objectives or hypotheses 3
22
23

24 **Trial design** [#8](#) Description of trial design including type of trial (eg, 2
25 parallel group, crossover, factorial, single group),
26 allocation ratio, and framework (eg, superiority,
27 equivalence, non-inferiority, exploratory)
28
29
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34 **Methods:**

35 **Participants,**
36
37 **interventions, and**
38
39 **outcomes**
40
41
42
43

44 **Study setting** [#9](#) Description of study settings (eg, community clinic, 4
45 academic hospital) and list of countries where data will be
46 collected. Reference to where list of study sites can be
47 obtained
48
49
50
51
52

53
54 **Eligibility criteria** [#10](#) Inclusion and exclusion criteria for participants. If 4
55 applicable, eligibility criteria for study centres and
56
57
58
59

1		individuals who will perform the interventions (eg,	
2			
3		surgeons, psychotherapists)	
4			
5			
6	Interventions:	#11a Interventions for each group with sufficient detail to allow	5-6
7			
8	description	replication, including how and when they will be	
9			
10		administered	
11			
12			
13	Interventions:	#11b Criteria for discontinuing or modifying allocated	5-6
14			
15	modifications	interventions for a given trial participant (eg, drug dose	
16		change in response to harms, participant request, or	
17		improving / worsening disease)	
18			
19			
20			
21			
22			
23	Interventions:	#11c Strategies to improve adherence to intervention protocols,	5-6
24			
25	adherence	and any procedures for monitoring adherence (eg, drug	
26		tablet return; laboratory tests)	
27			
28			
29			
30			
31	Interventions:	#11d Relevant concomitant care and interventions that are	5-6
32			
33	concomitant care	permitted or prohibited during the trial	
34			
35			
36	Outcomes	#12 Primary, secondary, and other outcomes, including the	6-7
37			
38		specific measurement variable (eg, systolic blood	
39		pressure), analysis metric (eg, change from baseline, final	
40		value, time to event), method of aggregation (eg, median,	
41		proportion), and time point for each outcome. Explanation	
42		of the clinical relevance of chosen efficacy and harm	
43		outcomes is strongly recommended	
44			
45			
46			
47			
48			
49			
50			
51			
52			
53	Participant timeline	#13 Time schedule of enrolment, interventions (including any	6-7
54			
55		run-ins and washouts), assessments, and visits for	
56			
57		participants. A schematic diagram is highly recommended	
58			
59			
60			

(see Figure)

1			
2			
3			
4	Sample size	#14	Estimated number of participants needed to achieve 4
5			
6			study objectives and how it was determined, including
7			
8			clinical and statistical assumptions supporting any sample
9			
10			size calculations
11			
12			
13	Recruitment	#15	Strategies for achieving adequate participant enrolment to 4
14			
15			
16			reach target sample size
17			
18			
19	Methods:		
20			
21	Assignment of		
22			
23	interventions (for		
24			
25	controlled trials)		
26			
27			
28			
29	Allocation: sequence	#16a	Method of generating the allocation sequence (eg, 4-5
30	generation		
31			computer-generated random numbers), and list of any
32			
33			factors for stratification. To reduce predictability of a
34			
35			random sequence, details of any planned restriction (eg,
36			
37			blocking) should be provided in a separate document that
38			
39			is unavailable to those who enrol participants or assign
40			
41			interventions
42			
43			
44			
45	Allocation	#16b	Mechanism of implementing the allocation sequence (eg, 4-5
46			
47	concealment		central telephone; sequentially numbered, opaque, sealed
48			
49	mechanism		envelopes), describing any steps to conceal the sequence
50			
51			until interventions are assigned
52			
53			
54			
55	Allocation:	#16c	Who will generate the allocation sequence, who will enrol 4-5
56			
57	implementation		participants, and who will assign participants to
58			
59			
60			

1		interventions	
2			
3			
4	Blinding (masking)	#17a Who will be blinded after assignment to interventions (eg,	4-5
5		trial participants, care providers, outcome assessors, data	
6		analysts), and how	
7			
8			
9			
10			
11	Blinding (masking):	#17b If blinded, circumstances under which unblinding is	4-5
12		emergency	
13		permissible, and procedure for revealing a participant's	
14	unblinding	allocated intervention during the trial	
15			
16			
17			
18			
19	Methods: Data		
20			
21	collection,		
22			
23	management, and		
24			
25	analysis		
26			
27			
28			
29	Data collection plan	#18a Plans for assessment and collection of outcome,	7
30		baseline, and other trial data, including any related	
31		processes to promote data quality (eg, duplicate	
32		measurements, training of assessors) and a description of	
33		study instruments (eg, questionnaires, laboratory tests)	
34		along with their reliability and validity, if known. Reference	
35		to where data collection forms can be found, if not in the	
36		protocol	
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48	Data collection plan:	#18b Plans to promote participant retention and complete	7
49	retention	follow-up, including list of any outcome data to be	
50		collected for participants who discontinue or deviate from	
51		intervention protocols	
52			
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57			
58	Data management	#19 Plans for data entry, coding, security, and storage,	7
59			
60			

including any related processes to promote data quality
(eg, double data entry; range checks for data values).

Reference to where details of data management
procedures can be found, if not in the protocol

10 Statistics: outcomes [#20a](#) Statistical methods for analysing primary and secondary 8-9

11 outcomes. Reference to where other details of the
12 statistical analysis plan can be found, if not in the protocol

18 Statistics: additional [#20b](#) Methods for any additional analyses (eg, subgroup and 8-9
19 analyses adjusted analyses)

23 Statistics: analysis [#20c](#) Definition of analysis population relating to protocol non- 8-9

24 population and adherence (eg, as randomised analysis), and any
25 missing data statistical methods to handle missing data (eg, multiple
26 imputation)

33 Methods: Monitoring

36 Data monitoring: [#21a](#) Composition of data monitoring committee (DMC); 7

37 formal committee summary of its role and reporting structure; statement of
38 whether it is independent from the sponsor and
39 competing interests; and reference to where further
40 details about its charter can be found, if not in the
41 protocol. Alternatively, an explanation of why a DMC is
42 not needed

53 Data monitoring: [#21b](#) Description of any interim analyses and stopping 7

54 interim analysis guidelines, including who will have access to these
55 interim results and make the final decision to terminate

1		the trial	
2			
3			
4	Harms	#22 Plans for collecting, assessing, reporting, and managing	7
5		solicited and spontaneously reported adverse events and	
6		other unintended effects of trial interventions or trial	
7		conduct	
8			
9			
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11			
12			
13	Auditing	#23 Frequency and procedures for auditing trial conduct, if	7
14		any, and whether the process will be independent from	
15		investigators and the sponsor	
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17			
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20			
21	Ethics and		
22			
23	dissemination		
24			
25			
26	Research ethics	#24 Plans for seeking research ethics committee / institutional	10
27		review board (REC / IRB) approval	
28	approval		
29			
30			
31	Protocol	#25 Plans for communicating important protocol modifications	10
32		(eg, changes to eligibility criteria, outcomes, analyses) to	
33	amendments	relevant parties (eg, investigators, REC / IRBs, trial	
34		participants, trial registries, journals, regulators)	
35			
36			
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41	Consent or assent	#26a Who will obtain informed consent or assent from potential	10
42		trial participants or authorised surrogates, and how (see	
43		Item 32)	
44			
45			
46			
47			
48			
49	Consent or assent:	#26b Additional consent provisions for collection and use of	Not
50		participant data and biological specimens in ancillary	
51	ancillary studies	studies, if applicable	applicable
52			
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57	Confidentiality	#27 How personal information about potential and enrolled	7
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participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial

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8	Declaration of	#28	Financial and other competing interests for principal
9			
10	interests		investigators for the overall trial and each study site
11			
12			
13	Data access	#29	Statement of who will have access to the final trial
14			
15			dataset, and disclosure of contractual agreements that
16			
17			limit such access for investigators
18			
19			
20			
21	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for
22			
23	trial care		compensation to those who suffer harm from trial
24			
25			participation
26			
27			
28	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial
29			
30	trial results		results to participants, healthcare professionals, the
31			
32			public, and other relevant groups (eg, via publication,
33			
34			reporting in results databases, or other data sharing
35			
36			arrangements), including any publication restrictions
37			
38			
39			
40			
41	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of
42			
43	authorship		professional writers
44			
45			
46	Dissemination policy:	#31c	Plans, if any, for granting public access to the full
47			
48	reproducible		protocol, participant-level dataset, and statistical code
49			
50			
51	research		
52			
53			
54	Appendices		
55			
56			
57	Informed consent	#32	Model consent form and other related documentation
58			
59			
60			

1 materials given to participants and authorised surrogates
2
3
4 Biological specimens [#33](#) Plans for collection, laboratory evaluation, and storage of Not
5
6 biological specimens for genetic or molecular analysis in applicable
7
8 the current trial and for future use in ancillary studies, if
9
10 applicable
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12

13 None The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative
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15
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