Dovigi Orthopaedic Sports Medicine Clinic
Sinai Health

UTOSM

The Effects of Preoperative Blood Flow Restriction Training in Patients Undergoing ACL Reconstruction

RESEARCH PACKAGE

Patient Name:

Patient Contact:

- Email: _____
- Cell: _____

Protocol Version 2.0:
October 28, 2022

Principle Investigator:
[redacted]
Resident Physician, Division of Orthopaedic Surgery, University of Toronto
[redacted]

Primary Supervisor:
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Staff Orthopaedic Surgeon, Mount Sinai Hospital, Toronto, ON

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MOUNT SINAI HOSPITAL
Joseph and Wolf Lebovic Health Complex

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: The Effects of Preoperative Blood Flow Restriction Training in Patients Undergoing ACL Reconstruction

INVESTIGATORS: [redacted]

Study Coordinator: [redacted]; Division of Orthopaedics, Department of Surgery, Women's College Hospital, Toronto, Ontario
(416) 323-7526

Introduction

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Background and Purpose

You are being asked to consider participating in this research study because you have a tear of your anterior cruciate ligament, and are electing to undergo anterior cruciate ligament reconstruction (ACLR) surgery. The purpose of the study is to explore the potential effect that pre-surgery physiotherapy with blood flow restriction training may have on improving the strength and function of your injured knee/leg.

Background:

The anterior cruciate ligament (ACL) is one of the most important ligaments in the knee as it controls joint stability. It is also one of the most commonly injured ligaments in young adults. ACL injury can result in joint instability and restriction of activities, even with physiotheraphy and other conservative treatment. Anterior cruciate ligament reconstruction (ACLR) is the surgical repair of this torn ligament, and can be done using 3 different grafts from the patients own body; the patellar tendon, the hamstring tendon, and the quadriceps tendon. All 3 graft types are commonly used, and your surgeon will have chosen the graft type they believed was best for you after examining you in clinic.

The quadricep femoris (QF) is a large group of muscle in the front of your thigh, muscle strength plays an important role in rehabilitation and overall outcome after lower limb injury or surgery. Weakening of this muscle group is common in patients with anterior cruciate ligament (ACL) injuries undergoing ACL reconstruction due to prior inactivity before surgery. In order to combat the challenges of the weakening of the quads muscle for patients with an ACL injury,

physiotherapy and in particular blood flow restriction (BFR) training during physiotherapy has been shown to have potential benefits for patients after their surgery. This method of treatment can help reduce the amount of quadriceps weakening by allowing muscles to maintain their strength and size while performing low load exercises. This is important as it is normally very difficult to rehabilitate these muscles with a painful and injured knee. Our study would like investigate, whether or not this form of training is beneficial prior to surgery so that patient's enter their operation with improved strength and function setting themselves up for success in the post operative period. If this study is able to demonstrate a positive outcome for patients prior to their surgery, blood flow restriction will prove to be a valuable training modality for all patients awaiting ACL reconstruction.

Study Design

If you consent to participate in this study, you will still receive normal standard of care treatment for your injury, no care will be denied. Your involvement in this study will last from the date you consent to participate during your appointment with your treating doctor to book surgery, until the week of your surgery. This time frame will vary depending on how far away the date of your surgery is, however the actual active time spent doing activities for this study will only be the 4 weeks leading up to your day of surgery.

In taking part in this study, you will be asked to participate in 4 weeks of physiotherapy, with 3 x 30 minute sessions per week for a total of 12 sessions, this will occur in the 4 weeks leading up to your surgery day. This is a randomized study, meaning participants will be randomized to one of two study groups for investigation. You will have a 50/50 chance of being randomized to either group, like the flip of a coin. Group 1, the experimental group, will have participants complete the course of pre-operative physiotherapy sessions while using blood flow restriction cuffs during their physiotherapy exercises, while group 2, the non-experimental group, will complete the same physiotherapy sessions but will not be using any additional devices during the exercises. All other study activities remain the same regardless of which group you have been randomized to.

You will also be asked to undergo physical examination of your knee including range of motion and strength testing, performed both manually by your care team, and on a machine called a Biodex. You will also be asked to complete two questionnaires that ask about the daily functioning ability of your knee, and your general health. These questionnaires and physical tests will only be done twice, once on the first day of your physiotherapy, and again on the last day of your physiotherapy. There are no study activities that take place after your surgery.

These physiotherapy sessions and strength testing sessions will be provided to you at no cost, however you may experience costs related to time and transit to attend these sessions. Every effort will be made to book these sessions on dates and times most convenient to you and your schedule.

The study team will consult your medical records to collect information such as your medical history and demographics (e.g., gender, date of birth) and take notes of the relevant information (data) for this research study.

Risks Related to Being in the Study

This study does not change any of the risks of treatment(s) that you may receive as part of your care. Blood flow restriction has been extensively reviewed and poses no greater
risk than traditional heavy-low training. All patients will be appropriately screened for

general health conditions that may impact their ability to participate in the project (e.g heart conditions, diabetes or severe high blood pressure).This study involves physical exercises and exams that if done correctly do not pose any significant risk, and will be supervised by medical professionals.

Benefits to Being in the Study

While you should not expect any direct benefits from participating in this study, it is possible benefits may exist from undergoing pre-operative physiotherapy. The data you provide during this study may have an impact on future outcomes for ACL reconstruction and this could help future patients who have an ACL tear.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your care You may refuse to answer any question you do not want to answer, or not answer an interview question by saying “pass”.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

Alternatives to Being in the Study

You do not have to participate in this study to continue to receive treatment for your anterior cruciate ligament tear. Full standard care will be provided to you regardless of your involvement in this study.

Confidentiality

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

- name,
- address,
- date of birth,
- new or existing medical records, that includes types, dates and results of medical tests or procedures.

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 7 years. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- Representatives of the study organizing committee.
- Mount Sinai Hospital Research Ethics Board.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you. You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

In Case You Are Harmed in the Study

If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Expenses Associated with Participating in the Study

You will not have to pay for any of the procedures involved with this study. You will not be reimbursed for transportation, meals, time, inconvenience, etc.

Conflict of Interest

The investigators have an interest in completing this study. Their interests should not influence your decision to participate in this study. You should not feel pressured to join this study.

Communication with Your Family Doctor

Your family doctor may be informed that you are taking part in this study so that your study doctor and family doctor can help you make informed decisions about your medical care.

Questions About the Study

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Dr. John Theodoropoulos at 416 586 4800, Ext. 8699 or the Study Coordinator, Shgufta Docter at 416-323-6400, Ext 7526

If you have any questions about your rights as a research participant or have concerns about this study, call Ronald Heslegrave, Ph. D., Chair of the Mount Sinai Hospital Research Ethics Board (REB) or the Research Ethics office number at 416-586-4875. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study {and to the use of my personal health information as described above}.

Print Study Participant's Name	Signature	Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions..

Print Name of Person Obtaining Consent	Signature	Date

Was the participant assisted during the consent process? ☐ **YES** ☐ **NO**

If **YES**, please check the relevant box and complete the signature space below:

☐ The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

Print Name of Translator	Signature	Date

Relationship to Participant	Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

Print Name of Witness	Signature	Date

Relationship to Participant

Patient Demographics

NAME: _____

AGE: _____

GENDER (circle): MALE FEMALE OTHER

WEIGHT (lbs): _____

LEG DOMINANCE: RIGHT LEFT

E.g. If you were to kick a soccer ball, which foot would you choose?

OCCUPATION: _____

PRIMARY SPORT: _____

PAST MEDICAL CONDITIONS:_____

MEDICATIONS: _____

Methods/Study Design

Group Allocation:

- Patients will be randomized into 1 of 2 groups:
  - **BFR Group**: BFR Physiotherapy Pre Operatively (16 patients)
  - **Non-BFR Group:** Same Physiotherapy protocol without BFR intervention Pre Operatively (16 patients)
- This will be a balanced randomization using an online randomization tool.

Inclusion Criteria:

- Sagittal Knee instability caused by ACL tear requiring surgical reconstruction
- Minimum 4 weeks since the time of injury
- Age 18 to 50 years
  - Range of motion required
    - Active extension deficit <5º, Active flexion > 120º
  - No previous surgery to affected knee

Exclusion Criteria:

- Functional impairment (neuro disease, gait abnormality, ambulatory aids at baseline)
- Severe spine or lower limb injuries
- Comorbidities including cardiovascular, respiratory or metabolic disease, blood coagulation disorders, current smoker

BFR Cuff Details:

- 14 cm wide contoured pneumatic tourniquet cuff (Delfi Easi-Fit Contour Thigh Cuff)
- Estimate best tourniquet fit based on patient's thigh circumference
  - RED = 18"
  - GREEN = 24'
  - BLUE = 34"
- Placed around proximal thigh, connected to portable pressure regulating system (Delfi Portable Tourniquet System)
- Inflated to 80% LOP (Limb Occlusion Pressure) – automatically performed with Delfi System

BFR Exercise Protocol: *To be completed at Mt. Sinai Hospital*

- Patient will perform a total of 12 sessions prior to surgery (3 sessions/week x 4 weeks)
- Patients will perform single leg knee extension exercise in a closed kinetic chain on a leg-press machine.
- Non injured leg will not perform any exercises but will act as control and be measured for strength and clinical outcome
- Patients in the non BFR group will perform the same protocol but there will be no inflation of their tourniquet during testing
- Load will be individually set to 15% 1RM for warm up and 25% 1RM for intervention
  - Warmup: 10 to 15 reps at 15% 1RM workload, no BFR occlusion
    - Rest: 30 seconds
  - 1st Set: cuff inflated to 80% LOP, patient completes 30 reps at 25% 1 RM
    - Rest: 30 seconds
  - 2nd Set: cuff remains inflated to 80% LOP, patient completes 15 reps at 25% 1RM
    - Rest: 30 seconds
  - 3rd Set: cuff remains inflated to 80% LOP, patient completes 15 reps at 25% 1RM
    - Rest: 30 seconds
  - 4th Set: cuff remains inflated to 80% LOP, patient completes 15 reps at 25% 1RM
    - Session complete, cuff deflated.
- Load Progression
  - If patient's are able to complete all 75 repetitions (30-15-15-15) on two consecutive sessions, their load will be increased by 10% at the subsequent session

Training Load Conversion Chart

TRAINING LOAD CHART											
Max reps (RM)	1	2	3	4	5	6	7	8	9	10	12
% 1RM	100%	95%	93%	90%	87%	85%	83%	80%	77%	75%	70%
Load	10	9.5	9.3	9	8.7	8.5	8.3	8	7.7	7.5	7
	20	19	18.6	18	17.4	17	16.6	16	15.4	15	14
	30	28.5	27.9	27	26.1	25.5	24.9	24	23.1	22.5	21
	40	38	37.2	36	34.8	34	33.2	32	30.8	30	28
	50	47.5	46.5	45	43.5	42.5	41.5	40	38.5	37.5	35
	60	57	55.8	54	52.2	51	49.8	48	46.2	45	42
	70	66.5	65.1	63	60.9	59.5	58.1	56	53.9	52.5	49
	80	76	74.4	72	69.6	68	66.4	64	61.6	60	56
	90	85.5	83.7	81	78.3	76.5	74.7	72	69.3	67.5	63
	100	95	93	90	87	85	83	80	77	75	70
	110	104.5	102.3	99	95.7	93.5	91.3	88	84.7	82.5	77
	120	114	111.6	108	104.4	102	99.6	96	92.4	90	84
	130	123.5	120.9	117	113.1	110.5	107.9	104	100.1	97.5	91
	140	133	130.2	126	121.8	119	116.2	112	107.8	105	98
	150	142.5	139.5	135	130.5	127.5	124.5	120	115.5	112.5	105
	160	152	148.8	144	139.2	136	132.8	128	123.2	120	112
	170	161.5	158.1	153	147.9	144.5	141.1	136	130.9	127.5	119
	180	171	167.4	162	156.6	153	149.4	144	138.6	135	126
	190	180.5	176.7	171	165.3	161.5	157.7	152	146.3	142.5	133
	200	190	186	180	174	170	166	160	154	150	140
	210	199.5	195.3	189	182.7	178.5	174.3	168	161.7	157.5	147
	220	209	204.6	198	191.4	187	182.6	176	169.4	165	154
	230	218.5	213.9	207	200.1	195.5	190.9	184	177.1	172.5	161
	240	228	223.2	216	208.8	204	199.2	192	184.8	180	168
	250	237.5	232.5	225	217.5	212.5	207.5	200	192.5	187.5	175
	260	247	241.8	234	226.2	221	215.8	208	200.2	195	182
	270	256.5	251.1	243	234.9	229.5	224.1	216	207.9	202.5	189
	280	266	260.4	252	243.6	238	232.4	224	215.6	210	196
	290	275.5	269.7	261	252.3	246.5	240.7	232	223.3	217.5	203
	300	285	279	270	261	255	249	240	231	225	210
	310	294.5	288.3	279	269.7	263.5	257.3	248	238.7	232.5	217
	320	304	297.6	288	278.4	272	265.6	256	246.4	240	224
	330	313.5	306.9	297	287.1	280.5	273.9	264	254.1	247.5	231
	340	323	316.2	306	295.8	289	282.2	272	261.8	255	238
	350	332.5	325.5	315	304.5	297.5	290.5	280	269.5	262.5	245
	360	342	334.8	324	313.2	306	298.8	288	277.2	270	252
	370	351.5	344.1	333	321.9	314.5	307.1	296	284.9	277.5	259
	380	361	353.4	342	330.6	323	315.4	304	292.6	285	266
	390	370.5	362.7	351	339.3	331.5	323.7	312	300.3	292.5	273
	400	380	372	360	348	340	332	320	308	300	280
	410	389.5	381.3	369	356.7	348.5	340.3	328	315.7	307.5	287
	420	399	390.6	378	365.4	357	348.6	336	323.4	315	294
	430	408.5	399.9	387	374.1	365.5	356.9	344	331.1	322.5	301
	440	418	409.2	396	382.8	374	365.2	352	338.8	330	308
	450	427.5	418.5	405	391.5	382.5	373.5	360	346.5	337.5	315
	460	437	427.8	414	400.2	391	381.8	368	354.2	345	322
	470	446.5	437.1	423	408.9	399.5	390.1	376	361.9	352.5	329
	480	456	446.4	432	417.6	408	398.4	384	369.6	360	336
	490	465.5	455.7	441	426.3	416.5	406.7	392	377.3	367.5	343
	500	475	465	450	435	425	415	400	385	375	350

- Training load chart can be used to calculate estimated 1-repetion maximum (1RM) values from multiple repetitions completed
  - For example, if an athlete completes 8 repetitions of the squat at 160 lbs, the estimated 1RM would be 200 lbs.
- Training load chart can also be used to assign intensity percentages for program design
  - For examaple, if an athlete's 1RM for the squat is 200 lbs, he/she should be able to successfully complete 10 repetitions of 150 lbs, or 75% max intensity.

Adapted from Landers, J. Maximum based on reps. *NSCA J* 6(6):60-61, 1984.

Participation Checklist

	Date	Supervisor	Completed	Comments
Patient Randomization		Lawrence Wengle	Y / N	BFR Group or CONTROL Group
Pre Intervention Biodex		Paul Papoutsakis	Y / N	
Pre Intervention Scores			Y / N	KOOS and SF-12 Questionnaires
BFR Session 1			Y / N	10RM = _____ 1RM = _____ 25% 1RM = _____ Thigh circumference _____mm
BFR Session 2			Y / N	
BFR Session 3			Y / N	
BFR Session 4			Y / N	
BFR Session 5			Y / N	
BFR Session 6			Y / N	
BFR Session 7			Y / N	
BFR Session 8			Y / N	
BFR Session 9			Y / N	
BFR Session 10			Y / N	
BFR Session 11			Y / N	
BFR Session 12			Y / N	Thigh circumference _____mm
Post Intervention Biodex		Paul Papoutsakis	Y / N	
Post Intervention Scores			Y / N	KOOS and SF-12 Questionnaires
ACL Surgery		Dr. Theodoropoulos	Y / N	

KOOS KNEE SURVEY

Today's date: _____/_____/_____ Date of birth: _____/_____/_____

Name: _____

INSTRUCTIONS: This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to perform your usual activities.
Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

Symptoms

These questions should be answered thinking of your knee symptoms during the **last week**.

S1. Do you have swelling in your knee?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S2. Do you feel grinding, hear clicking or any other type of noise when your knee moves?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S3. Does your knee catch or hang up when moving?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S4. Can you straighten your knee fully?

Always	Often	Sometimes	Rarely	Never
☐	☐	☐	☐	☐

S5. Can you bend your knee fully?

Always	Often	Sometimes	Rarely	Never
☐	☐	☐	☐	☐

Stiffness

The following questions concern the amount of joint stiffness you have experienced during the **last week** in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.

S6. How severe is your knee joint stiffness after first wakening in the morning?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

S7. How severe is your knee stiffness after sitting, lying or resting **later in the day**?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Pain

P1. How often do you experience knee pain?

Never	Monthly	Weekly	Daily	Always
☐	☐	☐	☐	☐

What amount of knee pain have you experienced the **last week** during the following activities?

P2. Twisting/pivoting on your knee

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P3. Straightening knee fully

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P4. Bending knee fully

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P5. Walking on flat surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P6. Going up or down stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P7. At night while in bed

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P8. Sitting or lying

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P9. Standing upright

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A1. Descending stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A2. Ascending stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A3. Rising from sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A4. Standing

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A5. Bending to floor/pick up an object

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A6. Walking on flat surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A7. Getting in/out of car

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A8. Going shopping

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A9. Putting on socks/stockings

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A10. Rising from bed

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A11. Taking off socks/stockings

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A12. Lying in bed (turning over, maintaining knee position)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A13. Getting in/out of bath

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A14. Sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A15. Getting on/off toilet

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A16. Heavy domestic duties (moving heavy boxes, scrubbing floors, etc)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A17. Light domestic duties (cooking, dusting, etc)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, sports and recreational activities

The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the **last week** due to your knee.

SP1. Squatting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP2. Running

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP3. Jumping

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP4. Twisting/pivoting on your injured knee

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP5. Kneeling

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Quality of Life

Q1. How often are you aware of your knee problem?

Never	Monthly	Weekly	Daily	Constantly
☐	☐	☐	☐	☐

Q2. Have you modified your life style to avoid potentially damaging activities to your knee?

Not at all	Mildly	Moderately	Severely	Totally
☐	☐	☐	☐	☐

Q3. How much are you troubled with lack of confidence in your knee?

Not at all	Mildly	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

Q4. In general, how much difficulty do you have with your knee?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Thank you very much for completing all the questions in this questionnaire.

KOOS KNEE SURVEY

Today's date: _____/_____/_____ Date of birth: _____/_____/_____

Name: _____

INSTRUCTIONS: This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to perform your usual activities.
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Symptoms

These questions should be answered thinking of your knee symptoms during the **last week**.

S1. Do you have swelling in your knee?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S2. Do you feel grinding, hear clicking or any other type of noise when your knee moves?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S3. Does your knee catch or hang up when moving?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S4. Can you straighten your knee fully?

Always	Often	Sometimes	Rarely	Never
☐	☐	☐	☐	☐

S5. Can you bend your knee fully?

Always	Often	Sometimes	Rarely	Never
☐	☐	☐	☐	☐

Stiffness

The following questions concern the amount of joint stiffness you have experienced during the **last week** in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.

S6. How severe is your knee joint stiffness after first wakening in the morning?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

S7. How severe is your knee stiffness after sitting, lying or resting **later in the day**?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Pain

P1. How often do you experience knee pain?

Never	Monthly	Weekly	Daily	Always
☐	☐	☐	☐	☐

What amount of knee pain have you experienced the **last week** during the following activities?

P2. Twisting/pivoting on your knee

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P3. Straightening knee fully

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P4. Bending knee fully

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P5. Walking on flat surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P6. Going up or down stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P7. At night while in bed

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P8. Sitting or lying

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P9. Standing upright

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A1. Descending stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A2. Ascending stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A3. Rising from sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A4. Standing

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A5. Bending to floor/pick up an object

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A6. Walking on flat surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A7. Getting in/out of car

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A8. Going shopping

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A9. Putting on socks/stockings

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A10. Rising from bed

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A11. Taking off socks/stockings

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A12. Lying in bed (turning over, maintaining knee position)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A13. Getting in/out of bath

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A14. Sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A15. Getting on/off toilet

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A16. Heavy domestic duties (moving heavy boxes, scrubbing floors, etc)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A17. Light domestic duties (cooking, dusting, etc)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, sports and recreational activities

The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the **last week** due to your knee.

SP1. Squatting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP2. Running

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP3. Jumping

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP4. Twisting/pivoting on your injured knee

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP5. Kneeling

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Quality of Life

Q1. How often are you aware of your knee problem?

Never	Monthly	Weekly	Daily	Constantly
☐	☐	☐	☐	☐

Q2. Have you modified your life style to avoid potentially damaging activities to your knee?

Not at all	Mildly	Moderately	Severely	Totally
☐	☐	☐	☐	☐

Q3. How much are you troubled with lack of confidence in your knee?

Not at all	Mildly	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

Q4. In general, how much difficulty do you have with your knee?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Thank you very much for completing all the questions in this questionnaire.

SF-12 Health Survey

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. **Answer each question by choosing just one answer**. If you are unsure how to answer a question, please give the best answer you can.

1. **In general, would you say your health is**:

☐1 Excellent ☐2 Very good ☐3 Good ☐4 Fair ☐5 Poor

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	YES, limited a lot	YES, limited a little	NO, not limited at all
2. **Moderate activities** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	☐1	☐2	☐3
3. Climbing **several** flights of stairs.	☐1	☐2	☐3

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	YES	NO
4. **Accomplished less** than you would like.	☐1	☐2
5. Were limited in the **kind** of work or other activities.	☐1	☐2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	YES	NO
6. **Accomplished less** than you would like.	☐1	☐2
7. Did work or activities **less carefully than usual**.	☐1	☐2

8. **During the past 4 weeks, how much did pain interfere with your normal work (including work outside the home and housework)?**

☐1 Not at all ☐2 A little bit ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

These questions are about how you have been feeling during the past 4 weeks.
For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm & peaceful?	☐1	☐2	☐3	☐4	☐5	☐6
10. Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5	☐6
11. Have you felt down-hearted and blue?	☐1	☐2	☐3	☐4	☐5	☐6

12. **During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?**

☐1 All of the time ☐2 Most of the time ☐3 Some of the time ☐4 A little of the time ☐5 None of the time

SF-12 Health Survey

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. **Answer each question by choosing just one answer**. If you are unsure how to answer a question, please give the best answer you can.

1. **In general, would you say your health is**:

□1 Excellent □2 Very good □3 Good □4 Fair □5 Poor

The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	YES, limited a lot	**YES, limited a little**	**NO, not limited at all**
2. **Moderate activities** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	□1	□2	□3
3. Climbing **several** flights of stairs.	□1	□2	□3

During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	YES	**NO**
4. **Accomplished less** than you would like.	□1	□2
5. Were limited in the **kind** of work or other activities.	□1	□2

During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	YES	**NO**
6. **Accomplished less** than you would like.	□1	□2
7. Did work or activities **less carefully than usual**.	□1	□2

8. **During the <u>past 4 weeks</u>, how much <u>did pain interfere</u> with your normal work (including work outside the home and housework)?**

□1 Not at all □2 A little bit □3 Moderately □4 Quite a bit □5 Extremely

These questions are about how you have been feeling during the <u>past 4 weeks</u>.
For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the <u>past 4 weeks</u>…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm & peaceful?	□1	□2	□3	□4	□5	□6
10. Did you have a lot of energy?	□1	□2	□3	□4	□5	□6
11. Have you felt down-hearted and blue?	□1	□2	□3	□4	□5	□6

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