Clinical Evaluation of the Levitation Knee Brace | Baseline

Start of Block: Survey Information

SI01
You are receiving this survey because you have volunteered and consented to be a participant in a research study. The purpose of the study is to examine and compare the effects of three different treatment interventions in individuals with knee osteoarthritis. Your responses to a series of health-related survey questions will be used to measure the effects of these treatment interventions.

The following survey incorporates questions from several different validated questionnaires that relate to knee pain, physical activity, quality of life, etc. Parts of these questionnaires cover overlapping topics. As a result, some of the questions in this survey will be **repetitive** in nature. Please be patient. It is important that you answer each question honestly and to the best of your ability. This survey should take approximately **30-45 minutes** of your time to complete. If you are unable to complete the entire survey in one sitting, please feel free to take a break and resume the survey at your next convenience at the survey link you were provided. Your responses will be **saved**. Thank you!

End of Block: Survey Information

Start of Block: Demographic Information

D01 What is your birth date?

	Day	Month	Year
Please select: (1)	▼ 1 (1 ... 31 (31)	▼ 1 (1 ... 12 (12)	▼ 1945 (1 ... 1976 (32)

Page Break

D02
The following questions are about sex at birth and gender. Sex refers to your sex assigned at birth. Gender refers to your gender identity, which may not necessarily correspond to what is indicated on legal documents.

D03 What was your sex assigned at birth?

- Female (1)
- Male (2)

D04 What is your gender?

- Woman (1)
- Man (2)
- Non-binary / third gender (3)
- Prefer not to say (4)

Page Break

D05 What is your ethnic origin? Select all that apply.

- [ ] African origin (1)
- [ ] Asian origins (2)
- [ ] Caribbean origins (3)
- [ ] North American Indigenous origins (4)
- [ ] European origins (5)
- [ ] Latin, Central and South American origins (6)
- [ ] Oceania origins (7)
- [ ] Other North American origin (8)
- [ ] Other (Please specify) (9) _____
- [ ] I prefer not to disclose (10)

Page Break

D06 What is your height in **feet** and **inches**?

	Feet	Inches
Please select: (1)	▼ 3 (1 ... 7 (7)	▼ 0 (1 ... 11 (11)

D07
Please enter your weight in either pounds or kilograms (e.g., for 176 lbs, enter: 176).

Select "pounds" to enter weight in pounds or "kilograms" to enter weight in kilograms.

- ○ pounds (lbs) (4) _____
- ○ kilograms (kg) (5) _____

Page Break

D08 Which best describes your current employment status?

- ○ Working (1)
- ○ In school (2)
- ○ Retired or semi-retired (3)
- ○ Assisting with someone else's care (4)
- ○ Unable to work (5)
- ○ Other (please specify) (6) _____

Display This Question:

If Which best describes your current employment status? = Unable to work

D09 Are you currently unable to work because of your knee condition?

- ○ Yes (1)
- ○ No (2)

D10 Comments on this section. If none, please leave blank.

_____

Page Break

End of Block: Demographic Information

Start of Block: Visual Analogue Scale

VAS01 This question features a scale (like a thermometer) on which “0” represents no pain and “100” represents the worst pain you can imagine. Please use the scale to identify the average severity of your knee pain you experienced **over the past week**.

If you experience pain in both of your knees during these activities, please answer with respect to your **${e://Field/AffectedKnee}** knee.

If you did not perform the activity in the past week, answer with your best estimate of how much pain the activity would cause you.

	No Pain — Worst Pain Imaginable 0 10 20 30 40 50 60 70 80 90 100
Pain during walking on a flat surface ()	
Pain during squatting ()	
Pain while going up or down stairs ()	
Pain rising from a seated position (including getting out of the car) ()	

Page Break

VAS02
This question deals with associated pain in regions of your body beyond your knee.

Do you experience pain in any of the following regions that began or worsened after the appearance of pain in your ${e://Field/AffectedKnee} knee? Please select all that apply.

Select "Other region(s)" to indicate up to 5 additional regions not listed below.

- [ ] Your ${e://Field/OtherSide} knee (1)
- [ ] Your ${e://Field/AffectedKnee} hip (2)
- [ ] Your ${e://Field/OtherSide} hip (3)
- [ ] Your ${e://Field/AffectedKnee} ankle (4)
- [ ] Your ${e://Field/OtherSide} ankle (5)
- [ ] Other region(s) (6)
- [ ] None (7)

Skip To: VAS04 If This question deals with associated pain in regions of your body beyond your knee. Do you exper... = None

VAS03 This question features a scale (like a thermometer) on which “0” represents no pain and “100” represents the worst pain you can imagine. Please use the scale to identify the average severity of pain you experienced in the following region(s) **over the past week**.

No Pain Worst Pain Imaginable

0 10 20 30 40 50 60 70 80 90 100

Your **${e://Field/OtherSide}** knee ()	
Your **${e://Field/AffectedKnee}** hip ()	
Your **${e://Field/OtherSide}** hip ()	
Your **${e://Field/AffectedKnee}** ankle ()	
Your **${e://Field/OtherSide}** ankle ()	
Other (Please specify region) ()	
Other (Please specify region) ()	
Other (Please specify region) ()	
Other (Please specify region) ()	
Other (Please specify region) ()	

Page Break

VAS04 Comments on this section. If none, please leave blank.

End of Block: Visual Analogue Scale

Start of Block: Knee Injury and Osteoarthritis Outcome Score

KOOS01 This part of the survey asks for your view about your **${e://Field/AffectedKnee}** 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 selecting the appropriate circle. If you are unsure about how to answer a question, please give the best answer you can.

Page Break

KOOS02 These questions should be answered thinking of your knee symptoms **during the last week.**

	Never (0)	Rarely (1)	Sometimes (2)	Often (3)	Always (4)
Do you have swelling in your knee? (1)	○	○	○	○	○
Do you feel grinding, hear clicking or any other type of noise when your knee moves? (2)	○	○	○	○	○
Does your knee catch or hang up when moving? (3)	○	○	○	○	○

Page Break

X→

KOOS03 These questions should be answered thinking of your knee symptoms (mobility) during the last week.

	Always (0)	Often (1)	Sometimes (2)	Rarely (3)	Never (4)
Can you straighten your knee fully? (1)	○	○	○	○	○
Can you bend your knee fully? (2)	○	○	○	○	○

X→

KOOS04 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.

	None (0)	Mild (1)	Moderate (2)	Severe (3)	Extreme (4)
How severe is your knee joint stiffness after first wakening in the morning? (1)	○	○	○	○	○
How severe is your knee stiffness after sitting, lying or resting **later in the day**? (2)	○	○	○	○	○

Page Break

KOOS05 The following questions concern the knee pain you experience.

	Never (0)	Monthly (1)	Weekly (2)	Daily (3)	Always (4)
How often do you experience knee pain? (1)	○	○	○	○	○

KOOS06 What amount of knee pain have you experienced in the last week during the following activities?

If you avoid an activity (e.g., twisting/pivoting or going up or down stairs) due to doctor's orders or because you choose to avoid the activity, select “Extreme”.

	None (0)	Mild (1)	Moderate (2)	Severe (3)	Extreme (4)
Twisting / pivoting on your knee (1)	○	○	○	○	○
Straightening knee fully (2)	○	○	○	○	○
Bending knee fully (3)	○	○	○	○	○
Walking on a flat surface (4)	○	○	○	○	○
Going up or down stairs (5)	○	○	○	○	○
At night while in bed (6)	○	○	○	○	○
Sitting or lying (7)	○	○	○	○	○
Standing upright (8)	○	○	○	○	○

Page Break

KOOS07 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 during the last week due to your knee.

If you avoid an activity (e.g., twisting/pivoting or going up or down stairs) due to doctor's orders or because you choose to avoid the activity, select “Extreme” for those items.

	None (0)	Mild (1)	Moderate (2)	Severe (3)	Extreme (4)
Descending stairs (1)	○	○	○	○	○
Ascending stairs (2)	○	○	○	○	○
Rising from sitting (3)	○	○	○	○	○
Standing (4)	○	○	○	○	○
Bending to floor / pick up an object (5)	○	○	○	○	○
Walking on a flat surface (6)	○	○	○	○	○
Getting in / out of car (7)	○	○	○	○	○
Going shopping (8)	○	○	○	○	○
Putting on socks / stockings (9)	○	○	○	○	○
Rising from bed (10)	○	○	○	○	○
Taking off stocks / stockings (11)	○	○	○	○	○
Lying in bed (turning over, maintaining knee position) (12)	○	○	○	○	○
Getting in / out of bath (13)	○	○	○	○	○
Sitting (14)	○	○	○	○	○

Getting on / off toilet (15)	○	○	○	○	○
Heavy domestic duties (moving heavy boxes, scrubbing floors, etc.) (16)	○	○	○	○	○
Light domestic duties (cooking, dusting, etc.) (17)	○	○	○	○	○

Page Break

KOOS08 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. If you avoid an activity (e.g., twisting/pivoting or going up or down stairs) due to doctor's orders or because you choose to avoid the activity, select “Extreme” for those items. If you do not normally engage in an activity (e.g., running or jumping), leave the item blank.

	None (0)	Mild (1)	Moderate (2)	Severe (3)	Extreme (4)
Squatting (1)	○	○	○	○	○
Running (2)	○	○	○	○	○
Jumping (3)	○	○	○	○	○
Twisting / pivoting on your injured knee (4)	○	○	○	○	○
Kneeling (5)	○	○	○	○	○

Page Break

KOOS09 The following questions concern your quality of life with your knee problem.

	Never (0)	Monthly (1)	Weekly (2)	Daily (3)	Constantly (4)
How often are you aware of your knee problem? (1)	○	○	○	○	○

KOOS10 These questions are concerned with your lifestyle with your knee problem.

	Not at all (0)	Mildly (1)	Moderately (2)	Severely (3)	Extremely (4)
Have you modified your lifestyle to avoid potentially damaging activities to your knee? (1)	○	○	○	○	○
How much are you troubled with lack of confidence in your knee? (2)	○	○	○	○	○

KOOS11 This question concerns your difficulty as a result of your knee problem.

	None (0)	Mild (1)	Moderate (2)	Severe (3)	Extreme (4)
In general, how much difficulty do you have with your knee? (1)	○	○	○	○	○

Page Break

KOOS12 Comments on this section. If none, please leave blank.

_____

End of Block: Knee Injury and Osteoarthritis Outcome Score

Start of Block: EQ-5D

EQ01
Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

- I have no problems in walking about (1)
- I have slight problems in walking about (2)
- I have moderate problems in walking about (3)
- I have severe problems in walking about (4)
- I am unable to walk about (5)

EQ02 SELF-CARE

- I have no problems washing or dressing myself (1)
- I have slight problems washing or dressing myself (2)
- I have moderate problems washing or dressing myself (3)
- I have severe problems washing or dressing myself (4)
- I am unable to wash or dress myself (5)

EQ03 USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities (1)
- I have slight problems doing my usual activities (2)
- I have moderate problems doing my usual activities (3)
- I have severe problems doing my usual activities (4)
- I am unable to do my usual activities (5)

EQ04 PAIN / DISCOMFORT

- I have no pain or discomfort (1)
- I have slight pain or discomfort (2)
- I have moderate pain or discomfort (3)
- I have severe pain or discomfort (4)
- I have extreme pain or discomfort (5)

EQ05 ANXIETY / DEPRESSION

- I am not anxious or depressed (1)
- I am slightly anxious or depressed (2)
- I am moderately anxious or depressed (3)
- I am severely anxious or depressed (4)
- I am extremely anxious or depressed (5)

Page Break

EQ06

We would like you to indicate on this scale how good or bad your own health is TODAY. The scale is numbered from 0 to 100. 100 means the best health you can imagine, 0 means the worse health you can imagine. Move the point on the scale to indicate how your health is TODAY.

	Worst imaginable health state									Best imaginable health state	
	0	10	20	30	40	50	60	70	80	90	100
Your own health state today ()											

Page Break

EQ07 Comments on this section. If none, please leave blank.

_____

End of Block: EQ-5D

Start of Block: Lower Extremity Activity Scale

LEAS01
This question relates to your current level of physical activity.

Please read through each description given below, pick the ONE description that best describes your regular daily activity.

- ○ I am confined to bed all day. (1)
- ○ I am confined to bed most of the day except for minimal transfer activities (going to the bathroom, etc.) (2)
- ○ I am either in bed or sitting in a chair most of the day. (3)
- ○ I sit most of the day, except for transfer activities, no walking or standing. (4)
- ○ I sit most of the day, but I stand occasionally and walk a minimum amount around the house. (I may rarely leave the house for an appointment and may require use of a wheelchair or scooter for transportation.) (5)
- ○ I walk around my house to a moderate degree but I don't leave the house on a regular basis. I may leave the house occasionally for an appointment. (6)
- ○ I walk around my house and go outside at will, walking one or two blocks at a time. (7)
- ○ I walk around my house, go outside at will and walk several blocks at a time without any assistance (weather permitting). (8)
- ○ I am up and about at will in my house and can go out and walk as much as I like with no restrictions (weather permitting). (9)
- ○ I am up and about at will in my house and outside. I also work inside the house in a *minimally* active job (10)
- ○ I am up and about at will in my house and outside. I also work inside the house in a *moderately* active job (11)
- ○ I am up and about at will in my house and outside. I also work inside the house in a *extremely* active job (12)
- ○ I am up and about at will in my house and outside. I also participate in *relaxed* physical activity such as jogging, dancing cycling swimming *occasionally* (2-3 times per month). (13)
- ○ I am up and about at will in my house and outside. I also participate in *relaxed* physical activity such as jogging, dancing cycling swimming *2-3 times per week*. (14)
- ○ I am up and about at will in my house and outside. I also participate in *relaxed* physical activity such as jogging, dancing cycling swimming *daily*. (15)

○ I am up and about at will in my house and outside. I also participate in *vigorous* physical activity such as jogging, dancing cycling swimming *occasionally (2-3 times per month)*. (16)

○ I am up and about at will in my house and outside. I also participate in *vigorous* physical activity such as jogging, dancing cycling swimming *2-3 times per week*. (17)

○ I am up and about at will in my house and outside. I also participate in *vigorous* physical activity such as jogging, dancing cycling swimming *daily*. (18)

LEAS02 Has the current situation with the COVID-19 pandemic increased or decreased your overall physical activity levels?

○ Increased greatly (1)

○ Increased slightly (2)

○ No change (3)

○ Decreased slightly (4)

○ Decreased greatly (5)

Page Break

LEAS03 Comments on this section. If none, leave blank.

_____

End of Block: Lower Extremity Activity Scale

Start of Block: Medication/Therapy

M/T01 Medications: Please indicate whether you have used the following medications in the **past month** to help treat your knee condition.

	Have you used this medication in the **last month**?

	Yes (1)	No (2)
Analgesics: Painkillers such as acetaminophen (Tylenol) (1)	○	○
NSAIDs: Non-steroidal anti-inflammatory painkillers such as aspirin, ibuprofen (Advil), naproxen (Aleve) (5)	○	○
Opioid analgesics: Painkillers such as tramadol (Tridural, Ralivia, Ultram) (6)	○	○
Topical analgesics: Creams, gels, and sprays used to treat pain such as capsaicin, lidocaine, benzocaine (8)	○	○

Page Break

M/T02 The medication(s) that you have selected in the previous question are listed below. For each medication please record how many days per week, and how many times per day you take the medication on those days, and how many pills (e.g., tablets, capsules) you take at a time.

If you accidentally selected a medication that you do not use, you can use the back arrow at the bottom of the page to return to the previous question and remove the selection.

	How many **days per week** do you take the medication?	How many **times per day** do you take the medication on those days?	How many **pills** (e.g., tablets, capsules) do you take **at a time**? For topical analgesics, leave this blank.
			(1)
Analgesics (1)	▼ 1 (1 ... 7 (7)	▼ 1 (1 ... 4+ (4)	
NSAIDs (5)	▼ 1 (1 ... 7 (7)	▼ 1 (1 ... 4+ (4)	
Opioid Analgesics (6)	▼ 1 (1 ... 7 (7)	▼ 1 (1 ... 4+ (4)	
Topical Analgesics (11)	▼ 1 (1 ... 7 (7)	▼ 1 (1 ... 4+ (4)	

M/T03 Comments on this section. If none, leave blank.

Page Break

M/T04 **Mobility Aids:** Please indicate if you have used any of these aids in the the **past month** to assist you with your knee condition.

	Have you used this aid in the **past month**?	
	Yes (1)	No (2)
Cane (1)	○	○
Walker (2)	○	○
Hiking Pole(s) (6)	○	○
Footwear (Orthotics) (3)	○	○
Other (5)	○	○

Page Break

M/T05 The walking aid(s) that you have selected in the previous question are listed below. For each aid please record how many days per week, and how many hours per day on average that you use the aid.

If you accidentally selected an aid you do not use, you can use the back arrow and remove the selection.

	How many **days per week** do you use this aid?	How many **hours per day** do you use this aid?
Cane (1)	▼ 1 (1 ... 7 (7)	▼ 1 (1 ... 18+ (18)
Walker (2)	▼ 1 (1 ... 7 (7)	▼ 1 (1 ... 18+ (18)
Hiking Pole(s) (7)	▼ 1 (1 ... 7 (7)	▼ 1 (1 ... 18+ (18)
Footwear (Orthotics) (3)	▼ 1 (1 ... 7 (7)	▼ 1 (1 ... 18+ (18)
Other (Please Specify) (4)	▼ 1 (1 ... 7 (7)	▼ 1 (1 ... 18+ (18)
Other (Please Specify) (5)	▼ 1 (1 ... 7 (7)	▼ 1 (1 ... 18+ (18)
Other (Please Specify) (6)	▼ 1 (1 ... 7 (7)	▼ 1 (1 ... 18+ (18)

M/T06 Comments on this section. If none, please leave blank.

Page Break

M/T07 **Allied Health Services**: Please indicate whether you have used the following therapies in the past month to help manage your knee pain.

If you use the therapy, please indicate how many times per month you use it.

	Have you used this therapy in the **past month**?		If you use the therapy, how many **times per month** do you use it?
	Yes (1)	No (2)	
Chiropractic Therapy (1)	○	○	▼ 1 (1 ... 11+ (11)
Massage Therapy (2)	○	○	▼ 1 (1 ... 11+ (11)
Occupational Therapy (3)	○	○	▼ 1 (1 ... 11+ (11)
Osteopathy (4)	○	○	▼ 1 (1 ... 11+ (11)
Physiotherapy (5)	○	○	▼ 1 (1 ... 11+ (11)
Podiatry (6)	○	○	▼ 1 (1 ... 11+ (11)
Acupuncture (7)	○	○	▼ 1 (1 ... 11+ (11)
Other (Please Specify) (8)	○	○	▼ 1 (1 ... 11+ (11)
Other (Please Specify) (9)	○	○	▼ 1 (1 ... 11+ (11)
Other (Please Specify) (10)	○	○	▼ 1 (1 ... 11+ (11)

M/T08 Comments on this section. If none, leave blank.

Page Break

M/T09 **Injections**: Please indicate whether you have received any of the following injections in the past 6 months to help manage your knee pain.

If you use the therapy, please indicate how many times **in the past 6 months** that you receive it.

	Have you used this therapy in the **past 6 months**?		If you use the therapy, how many times in the **last 6 months** have you use it?
	Yes (1)	No (2)	
Corticosteroid injections (1)	○	○	▼ 1 (1 ... 3+ (3)
Hyaluronic acid injections (Synvisc) (3)	○	○	▼ 1 (1 ... 3+ (3)
Platelet-rich plasma injections (4)	○	○	▼ 1 (1 ... 3+ (3)
Stem cell injections (5)	○	○	▼ 1 (1 ... 3+ (3)
Other (please specify) (8)	○	○	▼ 1 (1 ... 3+ (3)
Other (Please Specify) (9)	○	○	▼ 1 (1 ... 3+ (3)
Other (Please Specify) (10)	○	○	▼ 1 (1 ... 3+ (3)

M/T10 Comments on this section. If none, leave blank.

_____

Page Break

End of Block: Medication/Therapy

Start of Block: Pre-Intervention Expectations

PIE01
Prior to starting your treatment intervention (${e://Field/Cohort}) as part of the study protocol:
Do you expect your treatment intervention will relieve your knee pain?

- ○ No, not at all (1)
- ○ Yes, a little bit (2)
- ○ Yes, somewhat (3)
- ○ Yes, a moderate amount (4)
- ○ Yes, a lot (5)

PIE02 Comments on this section. If none, leave blank.

_____

End of Block: Pre-Intervention Expectations

Start of Block: Surgical Self-Prognosis

SSP01 Based on your current knee condition, what is your perceived need for total joint replacement surgery within the next 24 months?

- ○ Very low (1)
- ○ Low (2)
- ○ Moderate (3)
- ○ High (4)
- ○ Very high (5)

SSP02 Do you have plans to have total knee joint replacement surgery?

- ○ No (4)
- ○ Yes, I am on a waiting list (2)
- ○ Yes, I have a date for surgery (1)

SSP03 Comments on this section. If none please leave blank.

_____

End of Block: Surgical Self-Prognosis

Start of Block: End

END01 Thank you very much for completing the survey. You may go back and edit your responses. Once you are satisfied, press click the forward arrow to submit the survey.

A summary of your responses will be available after you submit the survey.

End of Block: End