

FORM NAME: BASELINE INTRO

CONTINUE

ARE YOU CONTINUING FROM CONSENT OR IS THIS A NEW PHONE CALL?

- 1, Continuing
- 2, New phone call

[IF CONTINUE=2] CONTACT

Hello. This is {INTNAME} calling from [SITE] about the BackInAction acupuncture study.

May I please speak with [FIRST_NAME]?

IF RESPONDENT NOT AVAILABLE

Generally are mornings, afternoons or evenings the best time to reach {RESPONDENT}?

SET TIME TO CALLBACK

CONFIRM

(Hello, this is {INTNAME} from Kaiser Permanente Research Institute/{SITE} calling about the BackInAction acupuncture study.)

I'm calling because you are due to complete your initial check-in for the BackInAction Study today. The survey will take about 60 minutes to complete. Is now (still) a good time?

IF NOT A GOOD TIME, SET TIME TO CALLBACK

[IF CONTINUE=1] BLR&B

You will receive \$15 as a thank you for completing the survey.

I want to remind you that answering these questions is voluntary. You can skip any question you don't want to answer. Your decision to answer or not answer the questions will not affect your care at [site] in any way, and none of the information you provide will be shared with your doctor or added to your medical record. Okay, let's get started.

REQDOB

Before we proceed, I need to collect your date of birth. This is important for us to have because after the survey, your date of birth will be used to randomly assign you to a study group, either acupuncture or usual care. What is your date of birth?

ENTER DOB:

IF R REFUSES DOB, RECORD AS A REFUSAL TO THE STUDY

AGE

[CALCULATE AGE BASED ON REQDOB]

RAND AGE

ASSIGN AGE GROUP BASED ON AGE – DO NOT ASK PARTICIPANT

- 1, 65-74
- 2, 75-84
- 3, 85+

CONFDOB

SHOW DOB GIVEN BY R: _____(mm/dd/yyyy)

Thank you. Let me read your date of birth back to you to check that I heard you correctly.

[READ BACK DOB]

- 1, DOB MATCHES
- 2, DOB DOES NOT MATCH (GO BACK AND RE-ENTER)

INELAGE CHECK

If Age (calculated var from DOB makes R ineligible—age<65) SKP INELAGE

If Age (calculated var from DOB makes R eligible—age>=65) SKIP TO Roland

[IF AGE<65] INELAGE

We appreciate your interest in the study. This study is only enrolling people over the age of 65.
Thank you for your time.

- 1 END CONTACT

Back pain related disability

FORM NAME: ROLAND

[IF AGE>=65] ROLAND

When your back hurts, you may or may not find it difficult to do some of the things you normally do. The first questions include statements that people sometimes use to describe themselves when they have back pain. Please think of the past week. Answer “yes” if the statement describes you and “no” if it does not. In the past week...

1. Roland Morris Disability Questionnaire	NO	YES	DK	REF
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Baseline Questionnaire – administered via phone

ROLAND_A I stay at home most of the time because of the pain in my back.	0	1	8	9
ROLAND_B I change position frequently to try and make my back comfortable.	0	1	8	9
ROLAND_C I walk more slowly than usual because of the pain in my back.	0	1	8	9
ROLAND_D Because of the pain in my back, I am not doing <u>any</u> of the jobs that I usually do around the house.	0	1	8	9
ROLAND_E Because of the pain in my back, I use a handrail to get upstairs.	0	1	8	9
ROLAND_F Because of the pain in my back, I lie down to rest more often.	0	1	8	9
ROLAND_G Because of the pain in my back, I have to hold on to something to get out of a reclining chair.	0	1	8	9
ROLAND_H Because of the pain in my back, I ask other people to do things for me.	0	1	8	9
ROLAND_I I get dressed more slowly than usual because of the pain in my back.	0	1	8	9
ROLAND_J I only stand up for short periods of time because of the pain in my back.	0	1	8	9
ROLAND_K Because of the pain in my back, I try not to bend or kneel down.	0	1	8	9
ROLAND_L I find it difficult to get out of a chair because of the pain in my back.	0	1	8	9

Baseline Questionnaire – administered via phone

ROLAND_M My back hurts most of the time.	0	1	8	9
ROLAND_N I find it difficult to turn over in bed because of the pain in my back.	0	1	8	9
ROLAND_O My appetite is not very good because of the pain in my back.	0	1	8	9
ROLAND_P I have trouble putting on my socks (or stockings) because of the pain in my back.	0	1	8	9
ROLAND_Q I only walk short distances because of the pain in my back.	0	1	8	9
ROLAND_R I sleep less well because of the pain in my back.	0	1	8	9
ROLAND_S Because of the pain in my back, I get dressed with help from someone else.	0	1	8	9
ROLAND_T I sit down for most of the day because of the pain in my back.	0	1	8	9
ROLAND_U I avoid heavy jobs around the house because of the pain in my back.	0	1	8	9
ROLAND_V Because of my back pain, I am more irritable and bad tempered with people.	0	1	8	9
ROLAND_W Because of the pain in my back, I go upstairs more slowly than usual.	0	1	8	9
ROLAND_X I stay in bed most of the time because of the pain in my back.	0	1	8	9

Pain intensity and pain interference

PEG

FORM NAME: PEG

The next few questions ask you to describe your lower back pain in the past week and how it may or may not interfere with your normal activities.

PEG_PAIN

What number best describes your pain on average in the past week, using a 0 to 10 scale where 0 is **no pain** and 10 is **pain as bad as you can imagine?** _____

88 DK

89 REF

PEG_INTERFERE

What number best describes how, in the past week, pain interfered with your enjoyment of life using a 0 to 10 scale where 0 is **does not interfere** and 10 is **completely interferes?**

88 DK

89 REF

PEG_OFTEN

What number best describes how, in the past week, pain interfered with your general activity using a 0 to 10 scale where 0 is **does not interfere** and 10 is **completely interferes?**

88 DK

89 REF

High impact chronic pain

FORM NAME: HIGH IMPACT CHRONIC PAIN

Those last questions were about the past week. Now, please think back a little further. These next questions are about your pain in the past three months.

PAIN_OFTEN

In the past 3 months, how often did you have pain?

- 0 Never
- 1 Some days
- 3 Most days
- 4 Every day
- 8 DK
- 9 REF

PAIN_LIMIT

Over the past 3 months how often did pain limit your life or work activities?

- 0 Never
- 1 Some days
- 3 Most days
- 4 Every day
- 8 DK
- 9 REF

Sciatica detection rule

FORM NAME: SCIATICA DETECTION RULE

The next questions ask about other physical symptoms related to your lower back pain.

SCIATICA_2

In the past month, have you had pain that travels down your leg below the knee?

1, ☐ **YES (CODE SCIATICA, SKP TO BACK PAIN-RELATED HEALTHCARE SERVICES)**

2, ☐ NO

(8) DK

(9) REF

SCIATICA_1

In the past month, have you had numbness or tingling in the leg or foot?

(1) ☐ **YES (CODE SCIATICA)** (0) ☐ NO (8) DK (9) REF

Back Pain-Related healthcare services

FORM NAME: BACK PAIN-RELATED HEALTHCARE SERVICES

These next questions are about your use of health services, products, and self-care practices to manage low back pain in in the past month.

TX_[FOLLOWED BY NAME INDICATED FOR EACH TX TYPE]

Have you used...[FILL TEXT FOR EACH]

- 1 Yes
- 0 No (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
- 8 DK (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
- 9 REF (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).

TX_[tx type]_LBP

Have you used this product for back pain or for other needs?

- 1 Yes, for back pain
- 2 Yes, but for other needs
- 8 DK
- 9 REF

TX_NSAIDS

Nonsteroidal anti-inflammatory drugs (NSAIDs) such as: Advil, Aleve, aspirin, Ibuprofen, Motrin, Naprosyn, naproxen, Voltaren

Tx_ACETA

Acetaminophen medications such as: Tylenol

TX_CANNABIS

Cannabis / Marijuana (including THC/CBD combination products)

TX_OTHER_CBD

Other CBD only products

TX_HERBAL

Herbs or nutritional supplements not including vitamins

We are now going to ask you about exercise and movement. We are interested in your **typical** patterns of exercise over the past month.

ACTIVE EXERCISE

During the past month, how often have you **exercised actively**, for example walking, cycling, swimming, jogging or active sports?

- 0 Not at all (SKIP TO **BACK EXERCISE**)
- 1 Less than once a week (SKIP TO **BACK EXERCISE**)

- 2 At least weekly (CONTINUE to **ACTIVE DAYS**)
- 8 DK [SKIP TO **BACK EXERCISE**]
- 9 REF [SKIP TO **BACK EXERCISE**]

ACTIVE DAYS

During the past month, in a typical week, how many days have you exercised actively?

- _____ Days (0-7 days)
- 8 DK
 - 9 REF

ACTIVE TIME

During the past month, on the days when you have exercised actively, how long have you exercised?

- _____ Hours (0-8) _____ Minutes (1-120 minutes) [AVERAGE
TIME IF DIFFERS BETWEEN DAYS]
- 998 DK
 - 999 REF

BACK EXERCISE

During the past month, how often have you done **low back exercises**?

- 0 Not at all (SKIP TO **MOVEMENT**)
- 1 Less than once a week (SKIP TO **MOVEMENT**)
- 2 At least weekly (CONTINUE to **BACK_DAYS**)
- 8 DK [SKIP TO **MOVEMENT**]
- 9 REF [SKIP TO **MOVEMENT**]

BACK DAYS During the past month, in a typical week, how many days have you done low back exercises?

- _____ Days (0-7 days)
- 8 DK
 - 9 REF

BACK TIME During the past month, on the days when you have done back exercises, how long have you exercised?

- _____ Hours (0-8) _____ Minutes (1-120 minutes) [AVERAGE
TIME IF DIFFERS BETWEEN DAYS]
- 998 DK
 - 999 REF

MOVEMENT

During the past month, how often have you engaged in **other movement-based therapies such as dance, Tai chi or yoga?**

- 0 Not at all (SKIP TO **TX SELF-MGMT**)
- 1 Less than once a week (SKIP TO **TX SELF-MGMT**)
- 2 At least weekly (CONTINUE to **MOVEMENT_DAYS**)
- 8 DK (SKIP TO **TX SELF-MGMT**)
- 9 REF (SKIP TO **TX SELF-MGMT**)

MOVEMENT_DAYS

During the past month, in a typical week, how many days have you engaged in other movement-based therapies?

_____ Days (0-7 days)

- 8 DK
- 9 REF

MOVEMENT_TIME

During the past month, on the days when you have engaged in other movement-based therapies, how long have you spent doing these therapies?

_____ Hours (0-8) _____ Minutes (1-120 minutes) [AVERAGE
TIME IF DIFFERS BETWEEN DAYS]

- 998 DK
- 999 REF

The next questions are about your use of programs or services for pain management for your low back pain in the **past month**.

Have you used...[FILL TEXT FOR EACH]

- 1 Yes
- 0 No (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
- 8 DK (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
- 9 REF (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).

TX_[tx type]_LBP

Have you used this program for back pain or for other needs?

- 1 Yes, for back pain

2 Yes, but for other needs

8 DK

9 REF

TX SELF-MGMT A structured self-management class or program led by a healthcare provider for pain, stress management, or something you might expect might help with pain management (such as mindfulness, meditation, pain education).

TX MIND BODY Mind-body techniques such as relaxed breathing, guided imagery, or progressive muscle relaxation on your own

TX ONLINE Online self-paced programs to manage pain [if NO, skip to TX_COUNSEL]

TX ONLINE NAME What is the name of the program(s) you used to manage pain?

TX COUNSEL Psychological counseling such as cognitive-behavioral therapy (either in person or by telephone or video visit)

NIH LBP Task Force Fear Avoidance

FORM NAME: FEAR AVOIDANCE

SAFE

Please say whether or not you agree with the following statement.

It's not really safe for a person with my back problem to be physically active

- ☐ 1 Agree
- ☐ 0 Disagree
- ☐ 8 DK
- ☐ 9 REF

HEAL CDE Pain Catastrophizing Questionnaire (6-item version)

FORM NAME: PAIN CATASTROPHIZING

These next few questions ask about the thoughts and feelings you may have when you are in pain. Please answer to what degree each statement describes your thoughts and feelings when you are experiencing pain. When I'm in pain...

	Not at all	To a Slight Degree	To a Moderate Degree	To a Great Degree	All the Time	DK	REF
HEAL_1 It's awful and I feel that it overwhelms me	0	1	2	3	4	8	9
HEAL_2 I feel I can't stand it anymore	0	1	2	3	4	8	9
HEAL_3 I become afraid that the pain will get worse	0	1	2	3	4	8	9
HEAL_4 I keep thinking about how much it hurts	0	1	2	3	4	8	9
HEAL_5 I keep thinking about how badly I want the pain to stop	0	1	2	3	4	8	9
HEAL_6 I wonder whether something serious may happen	0	1	2	3	4	8	9

EXPECT Patient Expectations of acupuncture

FORM NAME: EXPECTATIONS OF ACUPUNCTURE

EXPECT ACU

The next question asks about the effect that you think acupuncture may have on your life.

How much change do you realistically expect in the impact of back pain on your life? Please answer on a scale of 0 to 10, where 0 is “no change or worse”, and 10 is “back pain no longer impacts my life.” _____

DK=88, REF=89

HEAL CDE Sleep duration

Sleep Duration Question

PROMIS Sleep Disturbance 6a

FORM NAME: SLEEP DURATION

The next set of questions ask about your sleep patterns.

During the past month, about how many hours and minutes of actual sleep did you get each night? (This may be different than the number of hours and minutes you spent in bed).

SLEEP_H_HOURS____hours (0-15 hours) and SLEEP_M_MINUTES____minutes (0-59 minutes) of sleep per night

SLEEP_DK DK

SLEEP_REF REF

Sleep disturbance

HEAL CDE PROMIS

FORM NAME: PROMIS SLEEP DISTURBANCE

PROMIS_SLEEP_1

Please think of your sleep in the past week. In the past week, would you say...

	Very poor	Poor	Fair	Good	Very good	DK	REF
My sleep quality was	5	4	3	2	1	8	9

In the past week, would you say...

Baseline Questionnaire – administered via phone

	Not at all	A little bit	Somewhat	Quite a bit	Very much	DK	REF
PROMIS_SLEEP_2 My sleep was refreshing	5	4	3	2	1	8	9
PROMIS_SLEEP_3 I had a problem with my sleep	1	2	3	4	5	8	9
PROMIS_SLEEP_4 I had difficulty falling asleep	1	2	3	4	5	8	9
PROMIS_SLEEP_5 My sleep was restless	1	2	3	4	5	8	9
PROMIS_SLEEP_6 I tried hard to get to sleep	1	2	3	4	5	8	9

Fatigue

4-item PROMIS Fatigue measure (part of PROMIS®-29)

FORM NAME: PROMIS FATIGUE

Next are some questions about your energy level and fatigue in the past week. In the past week, would you say...

	Not at all	A little bit	Somewhat	Quite a bit	Very much	DK	REF
PROMIS_FATIGUE_1 I feel fatigued	1	2	3	4	5	8	9
PROMIS_FATIGUE_2 I have trouble <u>starting</u> things because I am tired	1	2	3	4	5	8	9
PROMIS_FATIGUE_3 How run-down did you feel on average?	1	2	3	4	5	8	9
PROMIS_FATIGUE_4 How fatigued were you on average?	1	2	3	4	5	8	9

Baseline Questionnaire – administered via phone

Physical functioning

PROMIS Physical Functioning Short Form 6b (part of PROMIS®-29)

FORM NAME: PROMIS PHYSICAL FUNCTION

For these next questions, please think of how your health may limit your physical activities. Even if you choose not to regularly engage in these activities, please answer if you **are able** to do the following...

Baseline Questionnaire – administered via phone

	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do	DK	REF
PROMIS_SF6B_1 Are you able to do chores such as vacuuming or yard work?	5	4	3	2	1	8	9
PROMIS_SF6B_2 Are you able to go up and down stairs at a normal pace?	5	4	3	2	1	8	9
PROMIS_SF6B_3 Are you able to go for a walk of at least 15 minutes?	5	4	3	2	1	8	9
PROMIS_SF6B_4 Are you able to run errands and shop?	5	4	3	2	1	8	9

The answer choices for the next two questions are a little different.

	Not at all	Very little	Somewhat	Quite a lot	Cannot do	DK	REF
PROMIS_SF6B_5 Does your health now limit you in doing two hours of physical labor?	5	4	3	2	1	8	9
PROMIS_SF6B_6 Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or carrying groceries?	5	4	3	2	1	8	9

PROMIS Social role functioning*PROMIS Ability to Participate in Social Roles 4A***FORM NAME: PROMIS SOCIAL ROLE**

Even if you choose not to regularly engage in these activities, please answer how often you **have trouble** doing the following...

	Never	Rarely	Sometimes	Usually	Always	DK	REF
PROMIS_SOCIAL_1 I have trouble doing all of my regular leisure activities with others	5	4	3	2	1	8	9
PROMIS_SOCIAL_2 I have trouble doing all of the family activities that I want to do	5	4	3	2	1	8	9
PROMIS_SOCIAL_3 I have trouble doing all of my usual work (include work at home)	5	4	3	2	1	8	9
PROMIS_SOCIAL_4 I have trouble doing all of the activities with friends that I want to do	5	4	3	2	1	8	9

Depression/Anxiety: 4-item PHQ4*HEAL CDE PHQ4***FORM NAME: PHQ4**

These next questions are about your mood. Over the last 2 weeks, how often have you been bothered by the following problems?

Baseline Questionnaire – administered via phone

	Not at all	Several days	More than half of days	Nearly every day	DK	REF
PHQ_1 Feeling nervous, anxious or on edge	0	1	2	3	8	9
PHQ_2 Not being able to stop or control worrying	0	1	2	3	8	9
PHQ_3 Little interest or pleasure in doing things	0	1	2	3	8	9
PHQ_4 Feeling down, depressed, or hopeless	0	1	2	3	8	9

IF SITE=KPWA OR SUTTER, SKIP TO EUROQUOL

IF SUM(3,4)>=3 && SITE=IFH, SKIP TO PHQ4_CONS

IF SUM(3,4)>=3 && SITE=KPNC, SKIP TO PHQ4_EMAIL

PHQ4 CONS

[IF SUM(3,4)>=3 && SITE=1]

It sounds like you have been feeling down [if possible, use a word patient used to describe their mood]. [pause for them to respond] I want to make sure you have support-- can I ask your provider to check in with you later today or tomorrow? They can hear more about how you're doing and offer some ideas for how you can feel better.

- IF **YES**: "Thanks, [pt name]. After our call, I'll message your provider through the IFH study team. How would you feel about continuing with the survey? [allow option to reschedule]"
- IF **NO**: "OK [pt name], no problem. How would you feel about continuing with the survey? [allow option to reschedule]"

1	YES
0	NO

- IF **YES**: "Thanks, [pt name]. After our call, I'll message your provider through the IFH study team. How would you feel about continuing with the survey? [allow option to reschedule]"

IF **NO**: “OK [pt name], no problem. How would you feel about continuing with the survey? [allow option to reschedule]”

[IF SUM(3,4)>=3]PHQ4 EMAIL [IFH, KPNC]

[IFH] System send email to IFH PI, PM, and CRC (Raymond Teets RTeets@institute.org, Matt Beyrouty Mbeyrouty@institute.org, and Phoebe Rosenheim prosenheim@institute.org) with participant’s studyID, Score, CONS = 0 or 1.

[KPNC] System send email to Gabriela Sanchez (Gabriela.X.Sanchez@kp.org) and Andy Avins (Andy.L.Avins@kp.org) with participant’s studyID and Score.

Health-Related Quality of Life for Economic Evaluation
EuroQuol-5D-5L

FORM NAME: EUROQUOL-5D-5L

EuroQuol-5D-5L phone version

We are trying to find out what you think about your health. I will explain what to do as I go along, but please interrupt me if you do not understand something or if things are not clear to you. There are no right or wrong answers. We are interested only in your personal view.

First, I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes your health TODAY.

Do not choose more than one answer in each group of questions.

EUROQUOL_1 First, I would like to ask you about mobility. Would you say that:

- 1 You have no problems walking?
- 2 You have slight problems walking?
- 3 You have moderate problems walking?
- 4 You have severe problems walking?
- 5 You are unable to walk?

EUROQUOL_2 Next, I would like to ask you about self-care. Would you say that:

- 1 You have no problems washing and dressing yourself?
- 2 You have slight problems washing and dressing yourself?
- 3 You have moderate problems washing and dressing yourself?
- 4 You have severe problems washing and dressing yourself?
- 5 You have unable to wash or dress yourself?

EUROQUOL_3 Next, I would like to ask you about usual activities, such as work, study,

housework, family or leisure activities. Would you say that:

- ☐ 1 You have no problems doing your usual activities?
- ☐ 2 You have slight problems doing your usual activities?
- ☐ 3 You have moderate problems doing your usual activities?
- ☐ 4 You have severe problems doing your usual activities?
- ☐ 5 You are unable to do your usual activities?

EUROQUOL_4 Next, I would like to ask you about pain or discomfort. Would you say that:

- 1 You have no pain or discomfort?
- 2 You have slight pain or discomfort?
- 3 You have moderate pain or discomfort?
- 4 You have severe pain or discomfort?
- 5 You have extreme pain or discomfort?

EUROQUOL_5 Finally, I would like to ask you about anxiety or depression. Would you say that:

- 1 You are not anxious or depressed?
- 2 You are slightly anxious or depressed?
- 3 You are moderately anxious or depressed?
- 4 You are severely anxious or depressed?
- 5 You are extremely anxious or depressed?

EUROQUOL_ HEALTH Now, I would like to ask you to say how good or bad your health is TODAY. I would like you to try to picture in your mind a scale that looks like a thermometer. The best health you can imagine is marked 100 (one hundred) at the top of the scale and the worst health you can imagine is marked 0 (zero) at the bottom. I would now like you to tell me the point on this scale where you would put your health TODAY.

ENTER R'S HEALTH TODAY: _____ (0-100)

998 DK

999 REF

Screening and Demographic-Measure(s)/Items

HEAL CDE Demographic questions + BMI

FORM NAME: DEMOGRAPHICS

I now have some general questions about you. You may skip any questions that you do not wish to answer.

For the next question, you can stop me when you hear the identity that describes you or you may wait until I have read the whole list to choose an answer.

GENDER_ID

What is your current gender identity?

- 1 Woman
- 2 Man
- 3 Transgender Woman/Transgender Female
- 4 Transgender Man/Transgender Male
- 5 Genderqueer
- 6 Something else (Please Specify): _____
- 8 DK
- 9 REF

SEX_BIRTH

What sex were you assigned at birth?

- 1 Male
- 2 Female
- 3 Intersex
- 4 Indeterminate or unknown
- 8 DK
- 9 REF

RAND_SEX

CHOOSE A VALUE BASED ON RESPONSE TO SEX AT BIRTH – DO NOT ASK PARTICIPANT

1, Male

2, Anything other than male

ETHNICITY

How do you describe your **ethnicity**?

- 1 Hispanic or Latino
- 2 Not Hispanic or Latino
- 3 Other, SPECIFY _____
- 8 DK
- 9 REF

RACE

How do you describe your **race**? (Mark all that apply)

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Pacific Islander

White

Other; please describe: _____

DK

REF

What is your height?

_____ **HT_FT** Height in ft (3-7 feet) and HT_INCH inches (0-12 inches)

or HT_M m (1-2) and HT_CM cm (0-10)

HT_NR DK=98, REF=99

WEIGHT What is your weight?

_____ **WEIGHT_LBS** Weight in pounds (50-450 lbs) or **WEIGHT_KG** kilograms (20-180 kg)

DK=998, REF=999

MARITAL_STATUS What category best describes your current relationship status?

- 1 Married
- 2 Domestic partner
- 3 Never married
- 4 Separated
- 5 Divorced
- 6 Widowed
- 8 DK
- 9 REF

EMPLOY What is your current employment status?

CODE ONLY ONE RESPONSE.

- 1 Working full-time
- 2 Working part-time
- 3 Retired [SKIP TO DISABILITY]
- 4 Homemaker [SKIP TO DISABILITY]
- 5 Unemployed or laid off [SKIP TO DISABILITY]
- 6 Unable to work [SKIP TO DISABILITY]
- 8 DK [SKIP TO DISABILITY]
- 9 REF [SKIP TO DISABILITY]

WORK_LIMIT Is your work limited or different because of pain or a pain condition? For example, not able to work, working from home, or changed type of work you do.

- 1 Yes
- 0 No
- 8 DK
- 9 REF

DISABILITY Have you ever applied for, or received, disability insurance for your low back pain?

- 1 Yes
- 0 No
- 8 DK
- 9 REF

EDUCATION What is the highest grade or level of school that you have completed?

- 1 Did not finish High School
- 2 High School Degree or GED
- 3 Vocational/Trade School
- 4 Some College, enrollment with no degree or Associate's degree – could include certificate
- 5 Completed Bachelor's degree
- 6 Some Graduate or Professional School
- 7 Completed Graduate or Professional School

8 DK

9 REF

INCOME What is your annual household income from all sources?

1 Less than \$10,000

2 \$10,000--- \$24,999

3 \$25,000--- \$34,999

4 \$35,000--- \$49,999

5 \$50,000--- \$74,999

6 \$75,000---\$99,999

7 \$100,000--- \$149,999

8 \$150,000--- \$199,999

9 \$200,000 or more

98 DK

99 REF

FRAIL Scale

FORM NAME: FRAIL SCALE

These next questions ask about your health.

FRAIL_1

Have you felt fatigue most or all of the time over the past month?

1 YES

0 NO

8 DK

9 REF

FRAIL_2

Do you have difficulty climbing a flight of stairs for reasons other than your back pain?

1 YES

0 NO

8 DK

9 REF

FRAIL_3

Do you have difficulty walking one block for reasons other than your back pain?

Baseline Questionnaire – administered via phone

- 1 YES
- 0 NO
- 8 DK
- 9 REF

If DK or REF for weight question above, skip to next question.

FRAIL_4

Have you lost more than X pounds (or kilos) [calculate 5 percent of participant weight] without dieting in the past year?

- 1 YES
- 0 NO
- 8 DK
- 9 REF

Tobacco, Alcohol, Prescription medications, and other Substance (TAPS)

HEAL CDE TAPS

FORM NAME: TAPS

The next few questions are about your tobacco and other substance use in the in the past year.

TOBACCO In the PAST 12 MONTHS, how often have you used any tobacco product-- for example, cigarettes, e-cigarettes, cigars, pipes, or smokeless tobacco?

- 0 - Daily or Almost Daily
- 1 - Weekly
- 2 - Monthly
- 3 - Less Than Monthly
- 4 – Never
- 8 DK
- 9 REF

BINGE In the PAST 12 MONTHS, how often have you had 5 (IF SEX_BIRTH = 1 (**MALE**) : **5**; IF SEX_BIRTH > 1 (**FEMALE/INTER/UNK/DK/REF**): **4**) or more drinks containing alcohol in one

day? One standard drink is about 1 small glass of wine (5 oz), 1 beer (12 oz), or 1 single shot of liquor.

0 - Daily or Almost Daily

1 - Weekly

2 - Monthly

3 - Less Than Monthly

4 - Never

8 DK

9 REF

DRUGS In the PAST 12 MONTHS, how often have you used any drugs including marijuana, cocaine or crack, heroin, methamphetamine or crystal meth, hallucinogens, ecstasy/MDMA?

0 - Daily or Almost Daily

1 - Weekly

2 - Monthly

3 - Less Than Monthly

4 – Never

8 DK

9 REF

RX_MISUSE In the PAST 12 MONTHS, how often have you used any prescription medications just for the feeling, more than prescribed or that were not prescribed for you? Prescription medications that may be used this way include:

- Opiate pain relievers (for example, OxyContin, Vicodin, Percocet, Methadone)
- Medications for anxiety or sleeping (for example, Xanax, Ativan, Klonopin)
- Medications for ADHD (for example, Adderall or Ritalin)

0 – Daily or Almost Daily

1 – Weekly

2 – Monthly

3 – Less Than Monthly

4 – Never

8 DK

9 REF

COVID19

FORM NAME: COVID19

We would like to know a little more about how you have been affected by the COVID-19 (coronavirus) pandemic. Please remember that any information you share is kept confidential.

COVID_1 Over the past 3 months, how has the COVID-19 pandemic changed your access to healthcare, including pain treatment, prescription and over-the-counter medications, medical and mental health visits, other treatments?

- 2 Reduced your ability to get healthcare A LOT
- 1 Reduced your ability to get healthcare A LITTLE
- 0 NOT AFFECTED your ability to get healthcare.
- 1 IMPROVED your ability to get healthcare.
- 8 DK
- 9 REF

COVID_2 Over the past 3 months, how has the COVID-19 pandemic affected your overall health including physical, mental and emotional health including pain?

- 2 Your overall health is A LOT WORSE.
- 1 Your overall health is A LITTLE WORSE.
- 0 NOT AFFECTED your overall health. (SKIP to Rand_consent)
- 1 IMPROVED your overall health. (SKIP to Rand_consent)
- 8 DK (SKIP to Rand_consent)
- 9 REF (SKIP to Rand_consent)

COVID_3 Please tell us a little more about how the COVID-19 pandemic has made your overall health [A LOT WORSE or A LITTLE WORSE; FILL RESPONSE FROM PREVIOUS Q]

Baseline closing

FORM NAME: CONFIRM CONTACT INFO

[IF SITE=2, 3, 4] ADDRESS CONFIRM

We have completed today's survey. We are sending/will send you \$15 as a thank you for completing this survey and enrolling in the study. This money will be added to a ClinCard, which you can use like a credit card. We will add money to this card when you complete other surveys for the study. Even if you use up all the money on your card, please keep it for when we add more money back on the card.

ADDITIONAL SCRIPTING TO READ BEFORE CLINCARDS ARE SETUP IF NEEDED:

Unfortunately, we are currently experiencing delays in sending ClinCards out to study participants. We are truly sorry for this inconvenience. We will have your ClinCard out to you as soon as possible but anticipate that it may take up to 4-6 weeks to receive your card.

Where shall we send the ClinCard?

CONFIRM OR UPDATE ADDRESS IN DATABASE

[IF SITE=1] ADDRESS CONFIRM

We have completed today's survey. Let's confirm where to send your \$15 compensation and find out your treatment group, and then we'll be done with today's call. We will add this money to a ClinCard, which is like a pre-paid debit card. We will add money to this card when you complete other surveys for the study. Even if you use up all the money on your card, please keep it for when we add more money back on the card.

IF CLINCARDS READY TO SEND, SKIP to NO

ADDITIONAL SCRIPTING TO READ BEFORE CLINCARDS ARE SETUP IF NEEDED:

Unfortunately, we are currently experiencing delays in sending ClinCards out to study participants. We anticipate it will take between 4-6 weeks for you to receive your ClinCard. You can wait to receive the card or we can offer you alternate payment methods until your ClinCard is ready. Would you be interested in one of these other methods?

[If YES] We can mail you cash or give it you in person at one of our clinics, or we can mail you a money order or give it to you in person, or we can send an Amazon gift card to your email address.

[If NO or if Additional scripting not needed] Would you like the ClinCard mailed to you or would you like to pick it up in person at an IFH clinic?

IF NEEDED:

You could pick it up at your first acupuncture visit should you be randomized to receive acupuncture, or if you are not randomized to receive acupuncture, you could pick it up at either our Harlem site, Manhattan site on West 17th St. or our Walton site in the South Bronx.

1, MAILED

2, PICK UP IN PERSON

[IF ADDRESS_CONFIRM=1] UPDATE_ADDRESS

Where shall we send the ClinCard?

CONFIRM OR UPDATE ADDRESS IN DATABASE

MONTH1

You will be contacted in one month for another phone survey that will take about 15 minutes.

PHONE

What is the best phone number to call?

UPDATE PRIMARY_PHONE ON CONTACT INFORMATION FORM/IN DATABASE

CONTACT BESTTIME

What are the best times and days to reach you? [OPEN TEXT FIELD]

UPDATE BEST_TIME ON CONTACT INFORMATION FORM/IN DATABASE

CONTACT NOTES

Is there anything else you'd like to share about the best way to reach you by phone? [OPEN TEXT FIELD ON CONTACT INFORMATION FORM/IN DATABASE]

FUTURE CONTACT

In case we can't reach you, is there someone else we can call to try to get in touch with you?

1 YES

0 NO SKP RAND_CONSENT

ALT_NAME

ENTER FIRST AND LAST NAME

ALT_NUMBER

ENTER ALTERNATIVE PHONE NUMBER

FORM NAME: RANDOMIZATION CONSENT

RAND_CONSENT

[IF SITE=3]

Thank you for completing the survey. As a reminder, the goal of the BackInAction study is to see if acupuncture can help older adults who have chronic low back pain improve their quality of life. We hope that the study will also help Medicare lower barriers to making acupuncture available for older people with low back pain. People who take part in the study will be randomly assigned to 1 of 3 groups. Two of the groups will get acupuncture, and the third group will get “usual care”. If you get “usual care”, we will ask that you not receive acupuncture during your enrollment in the study. We will use a computer to assign you to the acupuncture or usual care group. The group you are in will be decided by chance, like drawing names out of a hat. Do you have any questions?

We have a usual care group so we can compare it to the acupuncture groups to know if acupuncture works for people with low back pain. For the study to work, it's important that everyone stays in the group they are assigned to at the start of the study. If we don't have a usual care group, we won't be able to tell if acupuncture can help people. People that join the study and do **not** receive acupuncture (usual care group) are just as important to the study as people who join and receive acupuncture as part of their group assignment. Everyone is asked to do 12 monthly surveys to help us understand how you are doing over time. To ensure study results are accurate and valid, we need people in all groups who are willing to make this commitment so the study can be successful and improve the way we care for people with low back pain in the future. It's also important people are able to stay in the study, regardless of what group they're in, because the study may help Medicare determine the value of acupuncture for older adults with low back pain. This study is voluntary.

If you were assigned to the usual care group, which means you would **not receive acupuncture**, would you still be willing to stay in the study and complete the surveys? We want to make sure people that join are willing to take part and stay in the study, even if they don't receive acupuncture.

A member of the study team will call you within the next few days and let you know which group you are in and work with you on next steps. But first, I want to confirm you could commit to staying in the study if you get the usual-care or "no-acupuncture" group. Do you have any questions?

Are you ready to be randomly assigned to acupuncture or usual care?

1, YES

2, NO: Would you like a little more time to think about it? I or someone on our team can call you back in a couple days.

1, Yes: Set CB.

2, No: LOG REFUSAL REASON

[IF SITE=1,2,4]

Thank you for completing the survey. As a reminder, the goal of the BackInAction study is to see if acupuncture can help older adults who have chronic low back pain improve their quality of life. We hope that the study will also help Medicare lower barriers to making acupuncture available for older people with low back pain. People who take part in the study will be randomly assigned to 1 of 3 groups. Two of the groups will get acupuncture, and the third group will get “usual care”. If you get “usual care”, we will ask that you not receive acupuncture during your enrollment in the study. We will use a computer to assign you to the acupuncture or usual care group. The group you are in will be decided by chance, like drawing names out of a hat. Do you have any questions?

We have a usual care group so we can compare it to the acupuncture groups to know if acupuncture works for people with low back pain. For the study to work, it's important that everyone stays in the group they are assigned to at the start of the study. If we don't have a usual care group, we won't be able to tell if acupuncture can help people. People that join the study and do **not** receive acupuncture (usual care group) are just as important to the study as people who join and receive acupuncture as part of their group assignment. Everyone is asked to do 12 monthly surveys to help us understand how you are doing over time. To ensure study results are accurate and valid, we need people in all groups who are willing to make this commitment so the study can be successful and improve the way we care for people with low back pain in the future. It's also important people are able to stay in the study, regardless of what group they're in, because the study may help Medicare determine the value of acupuncture for older adults with low back pain. This study is voluntary.

If you were assigned to the usual care group, which means you would **not receive acupuncture**, would you still be willing to stay in the study and complete the surveys? We want to make sure people that join are willing to take part and stay in the study, even if they don't receive acupuncture.

Are you ready to be randomly assigned to acupuncture or usual care?

1, YES

2, NO: Would you like a little more time to think about it? I or someone on our team can call you back in a couple days.

1, Yes: Set CB.

2, No: LOG REFUSAL REASON

[IF RAND_CONSENT=2] THANKREF

IF R ALREADY GAVE REFUSAL REASON; DO NOT NEED TO ASK

It helps us with future studies to know the reasons people decide not to participate. Would you share your reasons?

RECORD PRIMARY REFUSAL REASON.

[IF RAND_CONSENT=2] TKSEXIT

Thank you for your time.

1 END CONTACT

[IF RAND_CONSENT=1] TKS QUESTIONS

Thank you for your participation, a member of our study team will call you in the next few days with your group assignment.

Do you have any questions? Please feel free to leave a voicemail at the study toll-free number at any time with questions. (IF NEEDED: The study toll-free number is 1- 877-750-8159.)

SUBMIT

CONTACT

Hello. This is {INTNAME} calling from Kaiser Permanente Research Institute/{SITE} about the BackInAction acupuncture study.

May I please speak with [RESPONDENT]?

1	R AVAILABLE/ COMES TO PHONE	SKP CONFIRM
---	-----------------------------	-------------

IF RESPONDENT NOT AVAILABLE

Generally are mornings, afternoons or evenings the best time to reach [RESPONDENT]?

3	INFORMANT KNOWS R, BUT NOT AT THIS NUMBER	EXIT, CODE WRONG #
4	NO SUCH PERSON	VERIDIAL
7	GET GENERAL BT & SET CB	EXIT, SET CB
8	R REFUSES INT	SKP THANKREF
9	SOME OTHER PROBLEM	EXIT

CONFIRM

(Hello, this is {INTNAME} from Kaiser Permanente Research Institute/{SITE} calling about the BackInAction acupuncture study.)

I want to remind you that as an interviewer for the study I'm not supposed to know whether you were randomized to acupuncture or usual care in the study. Please try not to tell me whether or not you received acupuncture as part of the study.

I'm calling because you are due to complete your 1-month check-in for the BackInAction Study. The survey will take about 15 minutes to complete. Is now still a good time?

1	YES	
7	NOT GOOD TIME, SET CB	EXIT, Set CB
8	REFUSES THIS INTERVIEW ONLY	SKP THANKREF
9	WANTS TO WITHDRAW FROM STUDY	SKP THANKREF

[KPWA/SUTTER/KPNC] RISKBENS

You will receive \$5 as a thank you for each completed monthly check-in, which we will add to your ClinCard at the end of the study. There are 9 monthly check-ins during the study; you may receive up to \$45 if you complete all 9 of them.

I want to remind you that answering these questions is voluntary. You can skip any question you don't want to answer. Your decision to answer or not answer the questions will not affect

1 Month Questionnaire – administered via phone

your care at [SITE] in any way, and none of the information you provide will be shared with your doctor or added to your medical record. Okay, let's get started.

1	CONTINUE	
7	NOT GOOD TIME, SET CB	EXIT, Set CB
8	REFUSES INTERVIEW	SKP THANKREF
9	WANTS TO WITHDRAW FROM STUDY	SKP THANKREF

[IFH] RISKBENS

You will receive \$5 as a thank you for each completed monthly check-in, which we will add to your ClinCard. There are 9 monthly check-ins during the study; you may receive up to \$45 if you complete all 9 of them.

I want to remind you that answering these questions is voluntary. You can skip any question you don't want to answer. Your decision to answer or not answer the questions will not affect your care at [SITE] in any way, and none of the information you provide will be shared with your doctor or added to your medical record. Okay, let's get started.

1	CONTINUE	
7	NOT GOOD TIME, SET CB	EXIT, Set CB
8	REFUSES INTERVIEW	SKP THANKREF
9	WANTS TO WITHDRAW FROM STUDY	SKP THANKREF

Pain intensity and pain interference

PEG

These first few questions ask you to describe your lower back pain in the past week and how it may or may not interfere with your normal activities.

PEG_PAIN

What number best describes your pain on average in the past week, using a 0 to 10 scale where 0 is **no pain** and 10 is **pain as bad as you can imagine?**

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

98 DK
99 REF

PEG_INTERFERE

What number best describes how, in the past week, pain interfered with your enjoyment of life using a 0 to 10 scale where 0 is **does not interfere** and 10 is **completely interferes**?

98 DK

99 REF

PEG_OFTEN

What number best describes how, in the past week, pain interfered with your general activity using a 0 to 10 scale where 0 is **does not interfere** and 10 is **completely interferes**?

98 DK

99 REF

Physical functioning

For these next questions, please think of how your health may limit your physical activities. Even if you choose not to regularly engage in these activities, please answer if you **are able** to do the following...

1 Month Questionnaire – administered via phone

	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do	DK	REF
PROMIS_SF6B_1 Are you able to do chores such as vacuuming or yard work?	5	4	3	2	1	8	9
PROMIS_SF6B_2 Are you able to go up and down stairs at a normal pace?	5	4	3	2	1	8	9
PROMIS_SF6B_3 Are you able to go for a walk of at least 15 minutes?	5	4	3	2	1	8	9
PROMIS_SF6B_4 Are you able to run errands and shop?	5	4	3	2	1	8	9

The answer choices for the next two questions are a little different.

	Not at all	Very little	Somewhat	Quite a lot	Cannot do	DK	REF
PROMIS_SF6B_5 Does your health now limit you in doing two hours of physical labor?	5	4	3	2	1	8	9
PROMIS_SF6B_6 Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or carrying groceries?	5	4	3	2	1	8	9

TICS

I am going to ask you some questions to test your memory. Some of these are likely to be easy for you, but some may be difficult. Please bear with me and try to answer all the questions as best you can. If you can't answer a question, don't worry. It is important that you give your best effort and your answers will not affect your participation in the study. We are asking these questions in this survey only. *For each of the actual TICS items, except item 5 and item 8, single repetitions are permitted.*

TICS_1. Please tell me your full name. [SHOW FIRST AND LAST NAME FROM RECORD]

	CORRECT	INCORRECT	DK	REF
TICS_1_FIRST:				
Provides first name	1	0	8	9
TICS_1_LAST:				
Provides last name	1	0	8	9

TICS_2a. What is today's date?
PROBE FOR MONTH, DAY, OR YEAR IF NOT VOLUNTEERED.

[SHOW] Month_____ [SHOW] Date_____ [SHOW] Year_____

	CORRECT	INCORRECT	DK	REF
TICS_2a_MONTH	1	0	8	9
TICS_2a_DATE	1	0	8	9
TICS_2a_YEAR	1	0	8	9

TICS_2b. What day of the week is it?

[SHOW] Day of the week: _____

	CORRECT	INCORRECT	DK	REF
TICS_2b_DAY	1	0	8	9

TICS_2c. What season is it?

[SHOW SEASON ACCORDING TO EQUINOX] Season: _____

	CORRECT	INCORRECT	DK	REF
TICS_2c_SEASON	1	0	8	9

TICS_3. What is your home address?
PROBE FOR HOUSE NUMBER, STREET, CITY, STATE, AND ZIP CODE IF NOT PROVIDED. (E.G., WHAT NUMBER IS THAT? WHAT IS YOUR ZIP CODE?)
[SHOW HOME ADDRESS FROM RECORD]

1 Month Questionnaire – administered via phone

	CORRECT	INCORRECT	DK	REF
TICS_3_HOUSE NUMBER	1	0	8	9
TICS_3_STREET	1	0	8	9
TICS_3_CITY	1	0	8	9
TICS_3_STATE	1	0	8	9
TICS_3_ZIP	1	0	8	9

TICS_4. Please count backward from 20 to 1.

IF PARTICIPANT MAKES AN ERROR, ASK THEM TO TRY AGAIN.

	CORRECT ON FIRST TRY	CORRECT ON SECOND TRY	INCORRECT	DK	REF
TICS_4_COUNT	2	1	0	8	9

TICS_5. I'm going to read you a list of 10 words. Please listen carefully and try to remember them. When I am done, tell me as many words as you can, in any order. Ready?

THE WORDS SHOULD BE READ AT APPROXIMATELY ONE WORD EVERY 2 SECONDS. NO REPETITIONS OF THE WORD LIST ARE PERMITTED.

The words are (PAUSE): cabin, pipe, elephant, chest, silk, theater, watch, whip, pillow, giant (PAUSE). Now tell me all the words you remember.

	NAMED	NOT NAMED	DK	REF
TICS_5_CABIN	1	0	8	9
TICS_5_PIPE	1	0	8	9
TICS_5_ELEPHANT	1	0	8	9
TICS_5_CHEST	1	0	8	9
TICS_5_SILK	1	0	8	9
TICS_5_THEATER	1	0	8	9
TICS_5_WATCH	1	0	8	9
TICS_5_WHIP	1	0	8	9
TICS_5_PILLOW	1	0	8	9
TICS_5_GIANT	1	0	8	9

TICS_6. I would like you to take the number 100 and subtract 7. (PAUSE). Now keep subtracting 7 from the answer until I tell you to stop.

NO FURTHER PROMPTS OF INSTRUCTIONS ARE GIVEN EXCEPT TO "KEEP GOING." STOP PARTICIPANT AFTER FIVE SERIAL SUBTRACTIONS. DO NOT INFORM R OF INCORRECT RESPONSES BUT ALLOW SUBTRACTIONS FROM LAST RESPONSE.

<Please just record the 5 serial subtractions.>

TICS_6_1: _____

TICS_6_2: _____

1 Month Questionnaire – administered via phone

TICS_6_3: _____

TICS_6_4: _____

TICS_6_5: _____

TICS_7a. What do people usually use to cut paper?

	CORRECT ("SCISSORS" OR "SHEARS")	INCORRECT	DK	REF
TICS_7a_CUT	1	0	8	9

TICS_7b. How many things are in a dozen?

	CORRECT ("12")	INCORRECT	DK	REF
TICS_7b_DOZEN	1	0	8	9

TICS_7c. What do you call the prickly green plant that lives in the desert?

	CORRECT ("CACTUS")	INCORRECT	DK	REF
TICS_7c_PRICKLY	1	0	8	9

TICS_7d. What animal does wool come from?

	CORRECT ("SHEEP" OR "LAMB")	INCORRECT	DK	REF
TICS_7d_WOOL	1	0	8	9

TICS_8a. Please repeat this after me: "No ifs, ands, or buts."

NO REPETITIONS OF THE PHRASES ARE PERMITTED UNLESS YOU MAKE A MISTAKE.

	CORRECT	INCORRECT	DK	REF
TICS_8a_IFS	1	0	8	9

TICS_8b. Say this: "Methodist Episcopal".

1 Month Questionnaire – administered via phone

NO REPETITIONS OF THE PHRASES ARE PERMITTED UNLESS YOU MAKE A MISTAKE.

	CORRECT	INCORRECT	DK	REF
TICS_8b_METHODIST	1	0	8	9

TICS_9a. Who is the President of the United States right now?
IF ONLY THE FIRST OR LAST NAME IS GIVEN, PROBE FOR THE FULL NAME.

	CORRECT FIRST AND LAST	CORRECT FIRST OR LAST ONLY	INCORRECT	DK	REF
TICS_9a_PRESIDENT	2	1	0	8	9

TICS_9b. Who is the Vice President of the United States right now? *IF ONLY THE FIRST OR LAST NAME IS GIVEN, PROBE FOR THE FULL NAME.*

	CORRECT FIRST AND LAST	CORRECT FIRST OR LAST ONLY	INCORRECT	DK	REF
TICS_9b_VICEPRESIDENT	2	1	0	8	9

TICS_10. With your finger, tap five times on the part of the phone you speak into.

	TAPS CLEARLY HEARD	EITHER MORE OR FEWER THAN 5 TAPS ARE HEARD	NO TAPS HEARD	DK	REF
TICS_10_TAPS	2	1	0	8	9

TICS_11. I am going to say a word and I want you to give me its opposite. For example, if I say “hot,” you would say “cold.”

11a. What is the opposite of “west”?

	CORRECT ("EAST")	INCORRECT	DK	REF
TICS_11a_WEST	1	0	8	9

1 Month Questionnaire – administered via phone

TICS_11b. What is opposite of “generous”? ACCEPT THE FOLLOWING WORDS AS CORRECT OR OTHER ANTONYMS YOU FEEL ARE APPROPRIATE.

	CORRECT	INCORRECT		
	(“SELFISH”			
	“GREEDY”			
	“STINGY”			
	“TIGHT”			
	“CHEAP”			
	“MEAN”			
	“MEAGER”			
	“SKIMPY”)		DK	REF
TICS_11b_GENEROUS	1	0	8	9

SKP THANKS

THANKREF

IF R ALREADY GAVE REFUSAL REASON; DO NOT NEED TO ASK

[IF DECLINING ONLY THIS INTERVIEW]: We will contact you for the 2-month check-in. Would you share your reasons for not wanting to do this interview?

RECORD PRIMARY REFUSAL REASON.

TKSEXIT

Thank you for being part of the Back in Action Study. We will contact you for the next check-in in about a month. Would you prefer to complete the check-in by web or phone?

- 1 Phone (SKIP TO PHONE)
- 2 Web (SKIP TO CONFIRM_EMAIL)
- 9 WANTS TO WITHDRAW FROM STUDY—COMPLETE STUDY WITHDRAWAL

SURVEY IN STUDY DATA GRID

[KPWA/KPNC/SUTTER]

THANKS

Thank you for your help today. As I mentioned earlier, you will receive \$5 as a thank you for completing this check-in at the end of the study. We will contact you for another short check-in next month. Would you prefer to complete the check-in by web or by phone?

- 1 Phone

1 Month Questionnaire – administered via phone

2 Web

9 WANTS TO WITHDRAW FROM STUDY—COMPLETE STUDY WITHDRAWAL
SURVEY IN STUDY DATA GRID

[IFH]

THANKS

Thank you for your help today. As I mentioned earlier, you will receive \$5 as a thank you for completing this check-in. We will contact you for another short check-in next month. Would you prefer to complete the check-in by web or by phone?

1 Phone

2 Web

9 WANTS TO WITHDRAW FROM STUDY—COMPLETE STUDY WITHDRAWAL
SURVEY IN STUDY DATA GRID

PHONE

What is the best number to reach you?

Home _____

Best number? [checkbox]

Mobile _____

Best number? [checkbox]

Work _____

Best number? [checkbox]

If THANKS=2, SKP CONFIRM_EMAIL

CONTACT BESTTIME

What are the best times and days to reach you? [OPEN TEXT FIELD]

CONTACT NOTES

Is there anything else you'd like to share about the best way to reach you by phone? [OPEN TEXT FIELD]

SKP Questions

[IF EMAIL COLLECTED EARLIER:]

CONFIRM EMAIL

Great! Is this the email address you'd like to use? [SHOW EMAIL ADDRESS ON FILE]

1 Yes [SKP Questions]

0 No

[IF CONFIRM_EMAIL = NO OR WE DO NOT HAVE ONE IN THE RECORD:]

Email1:

What email address would you like us to use? [OPEN TEXT WITH EMAIL FORMAT MASK]

Email2:

Please re-enter your email address. [OPEN TEXT WITH EMAIL FORMAT MASK]

[ADDRESSES WILL BE COMPARED FOR MATCH; IF THEY DO NOT, THERE WILL BE A PROMPT ASKING THAT THEY BE CHECKED AND CORRECTED]

[ALL SITES EXCEPT IFH] QUESTIONS

Do you have any questions? Please feel free to leave a voicemail at the study toll-free number at any time with questions. (IF NEEDED: The study toll-free number is 1-877-750-8159.)

[IFH] QUESTIONS

Do you have any questions? Please feel free to leave a voicemail at the study toll-free number at any time with questions. (IF NEEDED: The study toll-free number is 1-929-237-9821.)

1 **END CONTACT**

[IF MODE = WEB, SKIP TO WELCOME]

CONTACT

Hello. This is {INTNAME} calling from Kaiser Permanente Research Institute/{SITE} about the BackInAction acupuncture study.

May I please speak with {RESPONDENT}?

1	R AVAILABLE/ COMES TO PHONE	SKP CONFIRM
---	-----------------------------	-------------

IF RESPONDENT NOT AVAILABLE

we

Generally are mornings, afternoons or evenings the best time to reach {RESPONDENT}?

3	INFORMANT KNOWS R, BUT NOT AT THIS NUMBER	EXIT, CODE WRONG #
4	NO SUCH PERSON	VERIDIAL
7	GET GENERAL BT & SET CB	EXIT, SET CB
8	R REFUSES INT	SKP THANKREF
9	SOME OTHER PROBLEM	EXIT

CONFIRM

(Hello, this is {INTNAME} from Kaiser Permanente Research Institute/{SITE} calling about the BackInAction acupuncture study.)

I want to remind you that as an interviewer for the study I'm not supposed to know whether you were randomized to acupuncture or usual care in the study. Please try not to tell me whether or not you received acupuncture as part of the study.

I'm calling because you are due to complete your 3-month survey for the BackInAction Study. The survey will take about 50 minutes to complete. Is now still a good time?

1	YES	
7	NOT GOOD TIME, SET CB	EXIT, Set CB
8	REFUSES INTERVIEW	SKP THANKREF

RISK BENS

You will receive \$20 as a thank you for completing the survey.

I want to remind you that answering these questions is voluntary. You can skip any question you don't want to answer. Your decision to answer or not answer the questions will not affect

your care at [site] in any way, and none of the information you provide will be shared with your doctor or added to your medical record. Okay, let's get started.

1	CONTINUE	
7	NOT GOOD TIME, SET CB	EXIT, Set CB
8	REFUSES INTERVIEW	SKP THANKREF

[IF MODE = PHONE, SKIP TO ROLAND]

Web opening

Thank you for participating in the BackInAction research study! This survey should take about 50 minutes to complete. You will receive \$20 as a thank you for completing the survey.

Your participation is voluntary. You can skip any question you don't want to answer. Your decision to answer or not answer the questions will not affect your care at [site] in any way, and none of the information you provide will be shared with your doctor or added to your medical record.

[ALL SITES EXCEPT IFH] If you have any questions about the survey, please contact the study team at 1-877-750-8159.

[IFH] If you have any questions about the survey, please contact the study team at 1-929-237-9821.

Back pain related disability

ROLAND (all Roland items will be preceded by ROLAND)

When your back hurts, you may or may not find it difficult to do some of the things you normally do. The first questions include statements that people sometimes use to describe themselves when they have back pain. Please think of the past week. Answer "yes" if the statement describes you and "no" if it does not. In the past week...

1. Roland Morris Disability Questionnaire	NO	YES	DK	REF
--	-----------	------------	-----------	------------

3 Month Questionnaire – administered via phone or web

A. I stay at home most of the time because of the pain in my back.	0	1	8	9
B. I change position frequently to try and make my back comfortable.	0	1	8	9
C. I walk more slowly than usual because of the pain in my back.	0	1	8	9
D. Because of the pain in my back, I am not doing <u>any</u> of the jobs that I usually do around the house.	0	1	8	9
E. Because of the pain in my back, I use a handrail to get upstairs.	0	1	8	9
F. Because of the pain in my back, I lie down to rest more often.	0	1	8	9
G. Because of the pain in my back, I have to hold on to something to get out of a reclining chair.	0	1	8	9
H. Because of the pain in my back, I ask other people to do things for me.	0	1	8	9
I. I get dressed more slowly than usual because of the pain in my back.	0	1	8	9
J. I only stand up for short periods of time because of the pain in my back.	0	1	8	9
K. Because of the pain in my back, I try not to bend or kneel down.	0	1	8	9
L. I find it difficult to get out of a chair because of the pain in my back.	0	1	8	9

3 Month Questionnaire – administered via phone or web

M. My back hurts most of the time.	0	1	8	9
N. I find it difficult to turn over in bed because of the pain in my back.	0	1	8	9
O. My appetite is not very good because of the pain in my back.	0	1	8	9
P. I have trouble putting on my socks (or stockings) because of the pain in my back.	0	1	8	9
Q. I only walk short distances because of the pain in my back.	0	1	8	9
R. I sleep less well because of the pain in my back.	0	1	8	9
S. Because of the pain in my back, I get dressed with help from someone else.	0	1	8	9
T. I sit down for most of the day because of the pain in my back.	0	1	8	9
U. I avoid heavy jobs around the house because of the pain in my back.	0	1	8	9
V. Because of my back pain, I am more irritable and bad tempered with people.	0	1	8	9
W. Because of the pain in my back, I go upstairs more slowly than usual.	0	1	8	9
X. I stay in bed most of the time because of the pain in my back.	0	1	8	9

Pain intensity and pain interference

PEG

The next few questions ask you to describe your lower back pain in the past week and how it may or may not interfere with your normal activities.

[PHONE] PEG_PAIN

What number best describes your pain on average in the past week, using a 0 to 10 scale where 0 is **no pain** and 10 is **pain as bad as you can imagine**? _____

88 DK

89 REF

[ONLINE] PEG_PAIN

On a scale of 0 to 10 where 0 is no pain and 10 is pain as bad as you can imagine, what number best describes your pain on average in the past week?

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

[PHONE] PEG_INTERFERE

What number best describes how, in the past week, pain interfered with your enjoyment of life using a 0 to 10 scale where 0 is **does not interfere** and 10 is **completely interferes**?

8 DK

9 REF

[ONLINE] PEG_INTERFERE

On a scale of 0 to 10 where 0 does not interfere and 10 completely interferes, what number best describes how, in the past week, pain interfered with your enjoyment of life?

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

[PHONE] PEG_OFTEN

What number best describes how, in the past week, pain interfered with your general activity using a 0 to 10 scale where 0 is **does not interfere** and 10 is **completely interferes**?

- 8 DK
9 REF

[ONLINE] PEG_OFTEN

On a scale of 0 to 10 where 0 does not interfere and 10 completely interferes, what number best describes how, in the past week, pain interfered with your general activity?

☐ 0 Does not interfere	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Completely interferes
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Back Pain-Related healthcare services

These next questions are about your use of health services, products, and self-care practices to manage low back pain in in the **past month**.

TX_[FOLLOWED BY NAME INDICATED FOR EACH TX TYPE]

Have you used...[FILL TEXT FOR EACH]

- 1 Yes
0 No (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
8 DK (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
9 REF (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).

TX_[tx type]_LBP

Have you used this product for back pain or for other needs?

- 1 Yes, for back pain
2 Yes, but for other needs
8 DK
9 REF

NSAIDS

Nonsteroidal anti-inflammatory drugs (NSAIDs) such as: Advil, Aleve, aspirin, Ibuprofen, Motrin, Naprosyn, naproxen, Voltaren

ACETA

Acetaminophen medications such as: Tylenol

CANNABIS

Cannabis / Marijuana (including THC/CBD combination products)

OTHER_CBD

Other CBD only products

HERBAL

Herbs or nutritional supplements not including vitamins

We are now going to ask you about exercise and movement. We are interested in your **typical** patterns of exercise over the past month.

ACTIVE EXERCISE

During the past month, how often have you **exercised actively**, for example walking, cycling, swimming, jogging or active sports?

- 0 Not at all (SKIP TO **BACK EXERCISE**)
- 1 Less than once a week (SKIP TO **BACK EXERCISE**)
- 2 At least weekly (CONTINUE to **ACTIVE DAYS**)
- 8 DK [SKIP TO **BACK EXERCISE**]
- 9 REF [SKIP TO **BACK EXERCISE**]

ACTIVE DAYS

During the past month, in a typical week, how many days have you exercised actively?

_____ Days (0-7 days)

- 8 DK
- 9 REF

ACTIVE TIME

During the past month, on the days when you have exercised actively, how long have you exercised?

_____ Hours (0-8) _____ Minutes (1-120 minutes) [AVERAGE
TIME IF DIFFERS BETWEEN DAYS]

- 998 DK
- 999 REF

BACK EXERCISE

During the past month, how often have you done **low back exercises**?

- 0 Not at all (SKIP TO **MOVEMENT**)
- 1 Less than once a week (SKIP TO **MOVEMENT**)
- 2 At least weekly (CONTINUE to **BACK_DAYS**)
- 8 DK [SKIP TO **MOVEMENT**]
- 9 REF [SKIP TO **MOVEMENT**]

BACK_DAYS During the past month, in a typical week, how many days have you done low back exercises?

_____ Days (0-7 days)

- 8 DK
- 9 REF

BACK_TIME During the past month, on the days when you have done back exercises, how long have you exercised?

_____ Hours (0-8) _____ Minutes (1-120 minutes) [AVERAGE
TIME IF DIFFERS BETWEEN DAYS]

- 998 DK
- 999 REF

MOVEMENT

During the past month, how often have you engaged in **other movement-based therapies such as dance, Tai chi or yoga?**

- 0 Not at all (SKIP TO **TX_SELF-MGMT**)
- 1 Less than once a week (SKIP TO **TX_SELF-MGMT**)
- 2 At least weekly (CONTINUE to **MOVEMENT_DAYS**)
- 8 DK (SKIP TO **TX_SELF-MGMT**)
- 9 REF (SKIP TO **TX_SELF-MGMT**)

MOVEMENT_DAYS

During the past month, in a typical week, how many days have you engaged in other movement-based therapies?

_____ Days (0-7 days)

- 8 DK
- 9 REF

MOVEMENT_TIME

During the past month, on the days when you have engaged in other movement-based therapies, how long have you spent doing these therapies?

_____ Hours (0-8) _____ Minutes (1-120 minutes) [AVERAGE
TIME IF DIFFERS BETWEEN DAYS]
998 DK
999 REF

The next questions are about your use of programs or services for pain management for your low back pain in the **past month**.

Have you used...[FILL TEXT FOR EACH]

- 1 Yes
- 0 No (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
- 8 DK (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
- 9 REF (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).

TX_[tx type]_LBP

Have you used this program for back pain or for other needs?

- 1 Yes, for back pain
- 2 Yes, but for other needs
- 8 DK
- 9 REF

TX SELF-MGMT A structured self-management class or program led by a healthcare provider for pain, stress management, or something you might expect might help with pain management (such as mindfulness, meditation, pain education).

TX MIND BODY Mind-body techniques such as relaxed breathing, guided imagery, or progressive muscle relaxation on your own

TX ONLINE Online self-paced programs to manage pain [if NO, skip to TX_COUNSEL]

TX ONLINE NAME What is the name of the program(s) you used to manage pain?

TX COUNSEL Psychological counseling such as cognitive-behavioral therapy (either in person or by telephone or video visit)

Patient Global Impression of Change (PGIC)

For the next two questions please choose the answer that best describes your experience.

PGIC 1

Since the start of the study, my overall pain is

- 6 Much better
- 5 Moderately better
- 4 A little better
- 3 No change
- 2 A little worse
- 1 Moderately worse
- 0 Much worse
- 8 DK
- 9 REF

PGIC 2

Since the start of the study, how I am doing overall is

- 6 Much better
- 5 Moderately better
- 4 A little better
- 3 No change
- 2 A little worse
- 1 Moderately worse
- 0 Much worse
- 8 DK
- 9 REF

HEAL CDE Sleep duration

Sleep Duration Question

PROMIS Sleep Disturbance 6a

The next set of questions ask about your sleep patterns.

During the past month, about how many hours and minutes of actual sleep did you get each night? (This may be different than the number of hours and minutes you spent in bed).

SLEEP_H_HOURS____hours (0-15 hours) and SLEEP_M_MINUTES____minutes (0-59 minutes) of sleep per night

SLEEP_DK DK

SLEEP_REF REF

Fatigue

4-item PROMIS Fatigue measure (part of PROMIS®-29)

Next are some questions about your energy level and fatigue in the past week. In the past week, would you say...

	Not at all	A little bit	Somewhat	Quite a bit	Very much	DK	REF
PROMIS_FATIGUE_1 I feel fatigued	1	2	3	4	5	8	9
PROMIS_FATIGUE_2 I have trouble <u>starting</u> things because I am tired	1	2	3	4	5	8	9
PROMIS_FATIGUE_3 How run-down did you feel on average?	1	2	3	4	5	8	9
PROMIS_FATIGUE_4 How fatigued were you on average?	1	2	3	4	5	8	9

Physical functioning

PROMIS Physical Functioning Short Form 6b (part of PROMIS®-29)

For these next questions, please think of how your health may limit your physical activities. Even if you choose not to regularly engage in these activities, please answer if you **are able** to do the following...

3 Month Questionnaire – administered via phone or web

	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do	DK	REF
PROMIS_SF6B_1 Are you able to do chores such as vacuuming or yard work?	5	4	3	2	1	8	9
PROMIS_SF6B_2 Are you able to go up and down stairs at a normal pace?	5	4	3	2	1	8	9
PROMIS_SF6B_3 Are you able to go for a walk of at least 15 minutes?	5	4	3	2	1	8	9
PROMIS_SF6B_4 Are you able to run errands and shop?	5	4	3	2	1	8	9

[PHONE] The answer choices for the next two questions are a little different.

	Not at all	Very little	Somewhat	Quite a lot	Cannot do	DK	REF
PROMIS_SF6B_5 Does your health now limit you in doing two hours of physical labor?	5	4	3	2	1	8	9
PROMIS_SF6B_6 Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or carrying groceries?	5	4	3	2	1	8	9

PROMIS Social role functioning

PROMIS Ability to Participate in Social Roles 4A

Even if you choose not to regularly engage in these activities, please answer how often you **have trouble** doing the following...

	Never	Rarely	Sometimes	Usually	Always	DK	REF
PROMIS_SOCIAL_1 I have trouble doing all of my regular leisure activities with others	5	4	3	2	1	8	9
PROMIS_SOCIAL_2 I have trouble doing all of the family activities that I want to do	5	4	3	2	1	8	9
PROMIS_SOCIAL_3 I have trouble doing all of my usual work (include work at home)	5	4	3	2	1	8	9
PROMIS_SOCIAL_4 I have trouble doing all of the activities with friends that I want to do	5	4	3	2	1	8	9

Depression/Anxiety: 4-item PHQ4

HEAL CDE PHQ4

These next questions are about your mood. Over the last 2 weeks, how often have you been bothered by the following problems?

3 Month Questionnaire – administered via phone or web

	Not at all	Several days	More than half of days	Nearly every day	DK	REF
PHQ_1 Feeling nervous, anxious or on edge	0	1	2	3	8	9
PHQ_2 Not being able to stop or control worrying	0	1	2	3	8	9
PHQ_3 Little interest or pleasure in doing things	0	1	2	3	8	9
PHQ_4 Feeling down, depressed, or hopeless	0	1	2	3	8	9

IF SITE=KPWA OR SUTTER, SKIP TO EUROQUOL

IF SUM(3,4)>=3 && SITE=IFH, SKIP TO PHQ4_CONS

IF SUM(3,4)>=3 && SITE=KPNC, SKIP TO PHQ4_EMAIL

PHQ4 CONS

PHONE:

It sounds like you have been feeling down [if possible, use a word patient used to describe their mood]. [pause for them to respond] I want to make sure you have support-- can I ask your provider to check in with you later today or tomorrow? They can hear more about how you're doing and offer some ideas for how you can feel better.

WEB:

Based on your answers to the last few questions, it sounds like you have been feeling down. We on the study team want to make sure you have support-- can we ask your provider to check in with you later today or tomorrow? They can hear more about how you're doing and offer some ideas for how you can feel better.

1	YES
0	NO

PHONE:

3 Month Questionnaire – administered via phone or web

- IF **YES**: “Thanks, [pt name]. After our call, I’ll message your provider through the IFH study team. How would you feel about continuing with the survey? [allow option to reschedule]”
- IF **NO**: “OK [pt name], no problem. How would you feel about continuing with the survey? [allow option to reschedule]”

WEB:

- IF **YES**: “Thank you. After our call, your provider will be messaged through the IFH study team. Would you like to continue with the survey? [allow option to reschedule]”
- IF **NO**: “Thank you. Would you like to continue with the survey? [allow option to reschedule]”

PHQ4 EMAIL

[IFH] System send email to IFH PI, PM, and CRC (Raymond Teets RTeets@institute.org, Matt Beyrouty Mbeyrouty@institute.org, and Phoebe Rosenheim prosenheim@institute.org) with participant’s studyID, Score, CONS = 0 or 1.

[KPNC] System send email to Gabriela Sanchez (Gabriela.X.Sanchez@kp.org) and Andy Avins (Andy.L.Avins@kp.org) with participant’s studyID and Score.

Health-Related Quality of Life for Economic Evaluation *EuroQuol-5D-5L*

EuroQuol-5D-5L phone version

We are trying to find out what you think about your health. I will explain what to do as I go along, but please interrupt me if you do not understand something or if things are not clear to you. There are no right or wrong answers. We are interested only in your personal view.

First, I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes your health TODAY.

Do not choose more than one answer in each group of questions.

EUROQUOL_1 First, I would like to ask you about mobility. Would you say that:

- 1 You have no problems walking?
- 2 You have slight problems walking?
- 3 You have moderate problems walking?
- 4 You have severe problems walking?
- 5 You are unable to walk?

EUROQUOL_2 Next, I would like to ask you about self-care. Would you say that:

- 1 You have no problems washing and dressing yourself?
- 2 You have slight problems washing and dressing yourself?
- 3 You have moderate problems washing and dressing yourself?
- 4 You have severe problems washing and dressing yourself?
- 5 You have unable to wash or dress yourself?

EUROQUOL_3 Next, I would like to ask you about usual activities, such as work, study, housework, family or leisure activities. Would you say that:

- ☐ 1 You have no problems doing your usual activities?
- ☐ 2 You have slight problems doing your usual activities?
- ☐ 3 You have moderate problems doing your usual activities?
- ☐ 4 You have severe problems doing your usual activities?
- ☐ 5 You are unable to do your usual activities?

EUROQUOL_4 Next, I would like to ask you about pain or discomfort. Would you say that:

- 1 You have no pain or discomfort?
- 2 You have slight pain or discomfort?
- 3 You have moderate pain or discomfort?
- 4 You have severe pain or discomfort?
- 5 You have extreme pain or discomfort?

EUROQUOL_5 Finally, I would like to ask you about anxiety or depression. Would you say that:

- 1 You are not anxious or depressed?
- 2 You are slightly anxious or depressed?
- 3 You are moderately anxious or depressed?
- 4 You are severely anxious or depressed?
- 5 You are extremely anxious or depressed?

EUROQUOL_ HEALTH Now, I would like to ask you to say how good or bad your health is TODAY. I would like you to try to picture in your mind a scale that looks like a thermometer. The best health you can imagine is marked 100 (one hundred) at the top of the scale and the worst health you can imagine is marked 0 (zero) at the bottom. I would now like you to tell me the point on this scale where you would put your health TODAY.

ENTER R'S HEALTH TODAY: _____ (0-100)

998 DK

999 REF

Note to SRP: Please show each question on a different screen and show the following text on the top of every page.

Please click the ONE box that best describes your health TODAY.

EUROQUOL_1

MOBILITY

- | | | |
|---|----------------------------------|--------------------------|
| 1 | I have no problems walking | ☐ |
| 2 | I have slight problems walking | ☐ |
| 3 | I have moderate problems walking | ☐ |
| 4 | I have severe problems walking | ☐ |
| 5 | I am unable to walk | ☐ |

EUROQUOL_2

SELF-CARE

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

EUROQUOL_3

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

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

EUROQUOL_4

PAIN / DISCOMFORT

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

EUROQUOL_5

ANXIETY / DEPRESSION

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

We would like to know how good or bad your health is TODAY. This scale is numbered from 0 to 100. 100 means the best health you can imagine. 0 means the worst health you can imagine. Please click on the scale to indicate how your health is TODAY.

Note to SRP: Please see EQ-5D self-complete document for image of 100-point scale. The blank below should auto-populate when the participant clicks on the scale.

Your health today: _____ (0-100)

COVID19

We would like to know a little more about how you have been affected by the COVID-19 (coronavirus) pandemic. Please remember that any information you share is kept confidential.

COVID_1 Over the past 3 months, how has the COVID-19 pandemic changed your access to healthcare, including pain treatment, prescription and over-the-counter medications, medical and mental health visits, other treatments?

- 2 Reduced your ability to get healthcare A LOT
- 1 Reduced your ability to get healthcare A LITTLE
- 0 NOT AFFECTED your ability to get healthcare.
- 1 IMPROVED your ability to get healthcare.
- 8 DK
- 9 REF

A. COVID_2 Over the past 3 months, how has the COVID-19 pandemic affected your overall health including physical, mental and emotional health including pain?

- 2 Your overall health is A LOT WORSE.
- 1 Your overall health is A LITTLE WORSE.
- 0 NOT AFFECTED your overall health. (SKIP to THANKS)
- 1 IMPROVED your overall health. (SKIP to THANKS)
- 8 DK (SKIP to THANKS)
- 9 REF (SKIP to THANKS)

- B. COVID_3 Please tell us a little more about how the COVID-19 pandemic has made your overall health [A LOT WORSE or A LITTLE WORSE; FILL RESPONSE FROM PREVIOUS Q]
-

COVID_4 In the past 3 months, have you had a diagnosis of COVID-19 confirmed by a COVID-19 test?

[IF NO] SKIP TO TKSEXIT

[IF YES] COVID_5 Did you have a hospital stay for COVID-19 during this time?

[DISCOVERY SEND EMAIL WITH STUDYID, STUDYARM, COVID_5 to

Morgan.J.Fuoco@kp.org and Carolyn.m.eng@kp.org and KPWHRI---

BackInAction@kp.org]

THANKREF

IF R ALREADY GAVE REFUSAL REASON; DO NOT NEED TO ASK

[IF DECLINING ONLY THIS INTERVIEW]: We will contact you for the 4-month check-in. Would you share your reasons for not wanting to do this interview?

RECORD PRIMARY REFUSAL REASON.

TKSEXIT

Thank you for being part of the Back in Action Study. We will contact you for the next check-in in about a month. Would you prefer to complete the check-in by web or phone?

1 Phone (SKIP TO PHONE)

2 Web (SKIP TO PHONE)

9 WANTS TO WITHDRAW FROM STUDY—COMPLETE STUDY WITHDRAWAL

SURVEY IN STUDY DATA GRID

THANKS

Thank you for your help today. We will contact you for a short check-in next month. Would you prefer to complete the check-in by web or by phone?

1 Phone

2 Web

9 WANTS TO WITHDRAW FROM STUDY—COMPLETE STUDY WITHDRAWAL
SURVEY IN STUDY DATA GRID

PHONE

What is the best number to reach you?

Home _____ Best number? [checkbox]
Mobile _____ Best number? [checkbox]
Work _____ Best number? [checkbox]
IF THANKS=2 OR TKSEXIT=2, SKP CONFIRM_EMAIL

CONTACT BESTTIME

What are the best times and days to reach you? [OPEN TEXT FIELD]

CONTACT NOTES

Is there anything else you'd like to share about the best way to reach you by phone? [OPEN TEXT FIELD]

SKIP TO QUESTIONS

[IF EMAIL COLLECTED EARLIER:]

CONFIRM EMAIL

Great! Is this the email address you'd like to use? [SHOW EMAIL ADDRESS ON FILE]

1 YES [SKP Questions]
0 NO

[IF CONFIRM EMAIL = NO OR WE DO NOT HAVE ONE IN THE RECORD:]

Email1:

What email address would you like us to use? [OPEN TEXT WITH EMAIL FORMAT MASK]

Email2:

Please re-enter your email address. [OPEN TEXT WITH EMAIL FORMAT MASK]

[ADDRESSES WILL BE COMPARED FOR MATCH; IF THEY DO NOT, THERE WILL BE A PROMPT ASKING THAT THEY BE CHECKED AND CORRECTED]

CLINCARD

We will load \$20 on your ClinCard as a thank you for completing this survey. We will reload this card with money when you complete other surveys for the study. Even if you use up all the money on your card, please keep it for when we add more money to the card.

1	CONTINUE	SKIP TO QUESTIONS
2	LOST CLINCARD/NEEDS REPLACEMENT	[KPWA/KPNC/SH] SKIP TO ADDRESS CONFIRM [IFH] SKIP TO MAIL CLINCARD

MAIL CLINCARD

Would you like the new ClinCard mailed to you or would you like to pick it up in person at an IFH clinic?

[SHOW PPT ADDRESS ON RECORD]

2	PICK UP IN PERSON OR IF NO ADDRESS AVAILABLE	SKIP TO IFH PHONE, FILL MAILING ADDRESS AS IFH
1	MAILED AND ADDRESS SAME	SKIP TO QUESTIONS
0	MAILED AND UPDATE ADDRESS	SKIP TO NADDR

IFH PHONE

Please call the IFH study team at 1-929-237-9821 to coordinate a time for you to pick up your new ClinCard from the study team.

SKIP TO QUESTIONS

ADDRESS CONFIRM

Where shall we send the new ClinCard?

[SHOW PPT ADDRESS ON RECORD]

1	SAME ADDRESS	SKIP TO QUESTIONS
0	UPDATE ADDRESS	SKIP TO NADDR

NADDR

What is your new mailing address? NEWADDR1	SPECIFY
NEWADDR2	SPECIFY
NEWCITY	SPECIFY
NEWSTATE	SPECIFY

NEWZIP	SPECIFY
------------------------	-------------------------

[ALL SITES EXCEPT IFH] QUESTIONS

Do you have any questions? Please feel free to leave a voicemail at the study toll-free number at any time with questions. (IF NEEDED: The study toll-free number is 1-877-750-8159.)

[IFH] QUESTIONS

Do you have any questions? Please feel free to leave a voicemail at the study toll-free number at any time with questions. (IF NEEDED: The study toll-free number is 1-929-237-9821.)

1 END CONTACT

[IF MODE = WEB, SKIP WELCOME]

CONTACT

Hello. This is {INTNAME} calling from Kaiser Permanente Research Institute/{SITE} about the BackInAction acupuncture study.

May I please speak with {RESPONDENT}?

1	R AVAILABLE/ COMES TO PHONE	SKP CONFIRM
---	-----------------------------	-------------

IF RESPONDENT NOT AVAILABLE

Generally are mornings, afternoons or evenings the best time to reach {RESPONDENT}?

3	INFORMANT KNOWS R, BUT NOT AT THIS NUMBER	EXIT, CODE WRONG #
4	NO SUCH PERSON	VERIDIAL
7	GET GENERAL BT & SET CB	EXIT, SET CB
8	R REFUSES INT	SKP THANKREF
9	SOME OTHER PROBLEM	EXIT

CONFIRM

(Hello, this is {INTNAME} from Kaiser Permanente Research Institute/{SITE} calling about the BackInAction acupuncture study.)

I want to remind you that as an interviewer for the study I'm not supposed to know whether you were randomized to acupuncture or usual care in the study. Please try not to tell me whether or not you received acupuncture as part of the study.

I'm calling because you are due to complete your 6-month survey for the BackInAction Study. The survey will take about 50 minutes to complete. Is now still a good time?

1	YES	
7	NOT GOOD TIME, SET CB	EXIT, Set CB
8	REFUSES INTERVIEW	SKP THANKREF

RISKBENS

You will receive \$25 as a thank you for completing the survey.

I want to remind you that answering these questions is voluntary. You can skip any question you don't want to answer. Your decision to answer or not answer the questions will not affect your care at [site] in any way, and none of the information you provide will be shared with your doctor or added to your medical record. Okay, let's get started.

1	CONTINUE	
7	NOT GOOD TIME, SET CB	EXIT, Set CB
8	REFUSES INTERVIEW	SKP THANKREF

[IF MODE = PHONE, SKIP TO ROLAND]

Web opening

Thank you for participating in the BackInAction research study! This survey should take about 50 minutes to complete. You will receive \$25 as a thank you for completing the survey.

Your participation is voluntary. You can skip any question you don't want to answer. Your decision to answer or not answer the questions will not affect your care at [site] in any way, and none of the information you provide will be shared with your doctor or added to your medical record.

[ALL SITES EXCEPT IFH] If you have any questions about the survey, please contact the study team at 1-877-750-8159.

[IFH] If you have any questions about the survey, please contact the study team at 1-929-237-9821.

Back pain related disability

ROLAND (all Roland items will be preceded by ROLAND)

When your back hurts, you may or may not find it difficult to do some of the things you normally do. The first questions include statements that people sometimes use to describe themselves when they have back pain. Please think of the past week. Answer "yes" if the statement describes you and "no" if it does not. In the past week...

1. Roland Morris Disability Questionnaire	NO	YES	DK	REF
--	-----------	------------	-----------	------------

6 Month Questionnaire – administered via phone or web

A. I stay at home most of the time because of the pain in my back.	0	1	8	9
B. I change position frequently to try and make my back comfortable.	0	1	8	9
C. I walk more slowly than usual because of the pain in my back.	0	1	8	9
D. Because of the pain in my back, I am not doing <u>any</u> of the jobs that I usually do around the house.	0	1	8	9
E. Because of the pain in my back, I use a handrail to get upstairs.	0	1	8	9
F. Because of the pain in my back, I lie down to rest more often.	0	1	8	9
G. Because of the pain in my back, I have to hold on to something to get out of a reclining chair.	0	1	8	9
H. Because of the pain in my back, I ask other people to do things for me.	0	1	8	9
I. I get dressed more slowly than usual because of the pain in my back.	0	1	8	9
J. I only stand up for short periods of time because of the pain in my back.	0	1	8	9
K. Because of the pain in my back, I try not to bend or kneel down.	0	1	8	9
L. I find it difficult to get out of a chair because of the pain in my back.	0	1	8	9

6 Month Questionnaire – administered via phone or web

M. My back hurts most of the time.	0	1	8	9
N. I find it difficult to turn over in bed because of the pain in my back.	0	1	8	9
O. My appetite is not very good because of the pain in my back.	0	1	8	9
P. I have trouble putting on my socks (or stockings) because of the pain in my back.	0	1	8	9
Q. I only walk short distances because of the pain in my back.	0	1	8	9
R. I sleep less well because of the pain in my back.	0	1	8	9
S. Because of the pain in my back, I get dressed with help from someone else.	0	1	8	9
T. I sit down for most of the day because of the pain in my back.	0	1	8	9
U. I avoid heavy jobs around the house because of the pain in my back.	0	1	8	9
V. Because of my back pain, I am more irritable and bad tempered with people.	0	1	8	9
W. Because of the pain in my back, I go upstairs more slowly than usual.	0	1	8	9
X. I stay in bed most of the time because of the pain in my back.	0	1	8	9

Pain intensity and pain interference

PEG

The next few questions ask you to describe your lower back pain in the past week and how it may or may not interfere with your normal activities.

[PHONE] PEG_PAIN

What number best describes your pain on average in the past week, using a 0 to 10 scale where 0 is **no pain** and 10 is **pain as bad as you can imagine**? _____

89 DK

99 REF

[ONLINE] PEG_PAIN

On a scale of 0 to 10 where 0 is no pain and 10 is pain as bad as you can imagine, what number best describes your pain on average in the past week?

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

[PHONE] PEG_INTERFERE

What number best describes how, in the past week, pain interfered with your enjoyment of life using a 0 to 10 scale where 0 is **does not interfere** and 10 is **completely interferes**?

89 DK

99 REF

[ONLINE] PEG_INTERFERE

On a scale of 0 to 10 where 0 does not interfere and 10 completely interferes, what number best describes how, in the past week, pain interfered with your enjoyment of life?

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

[PHONE] PEG_OFTEN

What number best describes how, in the past week, pain interfered with your general activity using a 0 to 10 scale where 0 is **does not interfere** and 10 is **completely interferes**?

89 DK
99 REF

[ONLINE] PEG_OFTEN

On a scale of 0 to 10 where 0 does not interfere and 10 completely interferes, what number best describes how, in the past week, pain interfered with your general activity?

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

High impact chronic pain

Those last questions were about the past week. Now, please think back a little further. These next questions are about your pain in the past three months.

PAIN_OFTEN

In the past 3 months, how often did you have pain?

- 0 Never
- 1 Some days
- 3 Most days
- 4 Every day
- 8 DK
- 9 REF

PAIN_LIMIT

Over the past 3 months how often did pain limit your life or work activities?

- 0 Never
- 1 Some days
- 3 Most days
- 4 Every day
- 8 DK
- 9 REF

Back Pain-Related healthcare services

These next questions are about your use of health services, products, and self-care practices to manage low back pain in in the **past month**.

TX_[FOLLOWED BY NAME INDICATED FOR EACH TX TYPE]

Have you used...[FILL TEXT FOR EACH]

- 1 Yes
- 0 No (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
- 8 DK (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
- 9 REF (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).

TX_[tx type]_LBP

Have you used this product for back pain or for other needs?

- 1 Yes, for back pain
- 2 Yes, but for other needs
- 8 DK
- 9 REF

NSAIDS

Nonsteroidal anti-inflammatory drugs (NSAIDs) such as: Advil, Aleve, aspirin, Ibuprofen, Motrin, Naprosyn, naproxen, Voltaren

ACETA

Acetaminophen medications such as: Tylenol

CANNABIS

Cannabis / Marijuana (including THC/CBD combination products)

OTHER_CBD

Other CBD only products

HERBAL

Herbs or nutritional supplements not including vitamins

We are now going to ask you about exercise and movement. We are interested in your **typical** patterns of exercise over the past month.

ACTIVE EXERCISE

During the past month, how often have you **exercised actively**, for example walking, cycling, swimming, jogging or active sports?

- 0 Not at all (SKIP TO **BACK EXERCISE**)
- 1 Less than once a week (SKIP TO **BACK EXERCISE**)
- 2 At least weekly (CONTINUE to **ACTIVE DAYS**)
- 8 DK [SKIP TO **BACK EXERCISE**]
- 9 REF [SKIP TO **BACK EXERCISE**]

ACTIVE DAYS

During the past month, in a typical week, how many days have you exercised actively?

_____ Days (0-7 days)

- 8 DK
- 9 REF

ACTIVE TIME

During the past month, on the days when you have exercised actively, how long have you exercised?

_____ Hours (0-8) _____ Minutes (1-120 minutes) [AVERAGE
TIME IF DIFFERS BETWEEN DAYS]

- 998 DK
- 999 REF

BACK EXERCISE

During the past month, how often have you done **low back exercises**?

- 0 Not at all (SKIP TO **MOVEMENT**)
- 1 Less than once a week (SKIP TO **MOVEMENT**)
- 2 At least weekly (CONTINUE to **BACK_DAYS**)
- 8 DK [SKIP TO **MOVEMENT**]
- 9 REF [SKIP TO **MOVEMENT**]

BACK DAYS During the past month, in a typical week, how many days have you done low back exercises?

_____ Days (0-7 days)

- 8 DK
- 9 REF

BACK TIME During the past month, on the days when you have done back exercises, how long have you exercised?

_____ Hours (0-8) _____ Minutes (1-120 minutes) [AVERAGE
TIME IF DIFFERS BETWEEN DAYS]

998 DK

999 REF

MOVEMENT

During the past month, how often have you engaged in **other movement-based therapies such as dance, Tai chi or yoga?**

- 0 Not at all (SKIP TO **TX SELF-MGMT**)
- 1 Less than once a week (SKIP TO **TX SELF-MGMT**)
- 2 At least weekly (CONTINUE to **MOVEMENT_DAYS**)
- 8 DK (SKIP TO **TX SELF-MGMT**)
- 9 REF (SKIP TO **TX SELF-MGMT**)

MOVEMENT_DAYS

During the past month, in a typical week, how many days have you engaged in other movement-based therapies?

_____ Days (0-7 days)

8 DK

9 REF

MOVEMENT_TIME

During the past month, on the days when you have engaged in other movement-based therapies, how long have you spent doing these therapies?

_____ Hours (0-8) _____ Minutes (1-120 minutes) [AVERAGE
TIME IF DIFFERS BETWEEN DAYS]

998 DK

999 REF

The next questions are about your use of programs or services for pain management for your low back pain in the **past month**.

Have you used...[FILL TEXT FOR EACH]

- 1 Yes
- 0 No (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
- 8 DK (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).

9 REF (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).

TX_[tx type]_LBP

Have you used this program for back pain or for other needs?

- 1 Yes, for back pain
- 2 Yes, but for other needs
- 8 DK
- 9 REF

TX SELF-MGMT A structured self-management class or program led by a healthcare provider for pain, stress management, or something you might expect might help with pain management (such as mindfulness, meditation, pain education).

TX MIND BODY Mind-body techniques such as relaxed breathing, guided imagery, or progressive muscle relaxation on your own

TX ONLINE Online self-paced programs to manage pain [if NO, skip to TX_COUNSEL]

TX ONLINE NAME What is the name of the program(s) you used to manage pain?

TX COUNSEL Psychological counseling such as cognitive-behavioral therapy (either in person or by telephone or video visit)

Patient Global Impression of Change (PGIC)

For the next two questions please choose the answer that best describes your experience.

PGIC_1

Since the start of the study, my overall pain is

- 6 Much better
- 5 Moderately better
- 4 A little better
- 3 No change

- 2 A little worse
- 1 Moderately worse
- 0 Much worse
- 8 DK
- 9 REF

PGIC 2

Since the start of the study, how I am doing overall is

- 6 Much better
- 5 Moderately better
- 4 A little better
- 3 No change
- 2 A little worse
- 1 Moderately worse
- 0 Much worse
- 8 DK
- 9 REF

HEAL CDE Pain Catastrophizing Questionnaire (6-item version)

These next few questions ask about the thoughts and feelings you may have when you are in pain. Please answer to what degree each statement describes your thoughts and feelings when you are experiencing pain. When I'm in pain...

6 Month Questionnaire – administered via phone or web

	Not at all	To a Slight Degree	To a Moderate Degree	To a Great Degree	All the Time	DK	REF
HEAL_1 It's awful and I feel that it overwhelms me	0	1	2	3	4	8	9
HEAL_2 I feel I can't stand it anymore	0	1	2	3	4	8	9
HEAL_3 I become afraid that the pain will get worse	0	1	2	3	4	8	9
HEAL_4 I keep thinking about how much it hurts	0	1	2	3	4	8	9
HEAL_5 I keep thinking about how badly I want the pain to stop	0	1	2	3	4	8	9
HEAL_6 I wonder whether something serious may happen	0	1	2	3	4	8	9

HEAL CDE Sleep duration

Sleep Duration Question

PROMIS Sleep Disturbance 6a

The next set of questions ask about your sleep patterns.

During the past month, about how many hours and minutes of actual sleep did you get each night? (This may be different than the number of hours and minutes you spent in bed).

SLEEP_H_HOURS___hours (0-15 hours) and SLEEP_M_MINUTES___minutes (0-59 minutes) of sleep per night

SLEEP_DK DK

SLEEP_REF REF

Sleep disturbance

HEAL CDE PROMIS

PROMIS_SLEEP_1

Please think of your sleep in the past week. In the past week, would you say...

6 Month Questionnaire – administered via phone or web

	Very poor	Poor	Fair	Good	Very good	DK	REF
My sleep quality was	5	4	3	2	1	8	9

In the past week, would you say...

	Not at all	A little bit	Somewhat	Quite a bit	Very much	DK	REF
PROMIS_SLEEP_2 My sleep was refreshing	5	4	3	2	1	8	9
PROMIS_SLEEP_3 I had a problem with my sleep	1	2	3	4	5	8	9
PROMIS_SLEEP_4 I had difficulty falling asleep	1	2	3	4	5	8	9
PROMIS_SLEEP_5 My sleep was restless	1	2	3	4	5	8	9
PROMIS_SLEEP_6 I tried hard to get to sleep	1	2	3	4	5	8	9

social

4-item PROMIS Fatigue measure (part of PROMIS® -29)

Next are some questions about your energy level and fatigue in the past week. In the past week, would you say...

	Not at all	A little bit	Somewhat	Quite a bit	Very much	DK	REF
PROMIS_FATIGUE_1 I feel fatigued	1	2	3	4	5	8	9

6 Month Questionnaire – administered via phone or web

PROMIS_FATIGUE_2						8	9
I have trouble <u>starting</u> things because I am tired	1	2	3	4	5		
PROMIS_FATIGUE_3						8	9
How run-down did you feel on average?	1	2	3	4	5		
PROMIS_FATIGUE_4						8	9
How fatigued were you on average?	1	2	3	4	5		

Physical functioning

PROMIS Physical Functioning Short Form 6b (part of PROMIS®-29)

For these next questions, please think of how your health may limit your physical activities. Even if you choose not to regularly engage in these activities, please answer if you **are able** to do the following...

6 Month Questionnaire – administered via phone or web

	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do	DK	REF
PROMIS_SF6B_1 Are you able to do chores such as vacuuming or yard work?	5	4	3	2	1	8	9
PROMIS_SF6B_2 Are you able to go up and down stairs at a normal pace?	5	4	3	2	1	8	9
PROMIS_SF6B_3 Are you able to go for a walk of at least 15 minutes?	5	4	3	2	1	8	9
PROMIS_SF6B_4 Are you able to run errands and shop?	5	4	3	2	1	8	9

[PHONE] The answer choices for the next two questions are a little different.

	Not at all	Very little	Somewhat	Quite a lot	Cannot do	DK	REF
PROMIS_SF6B_5 Does your health now limit you in doing two hours of physical labor?	5	4	3	2	1	8	9
PROMIS_SF6B_6 Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or carrying groceries?	5	4	3	2	1	8	9

PROMIS Social role functioning*PROMIS Ability to Participate in Social Roles 4A*

Even if you choose not to regularly engage in these activities, please answer how often you **have trouble** doing the following...

	Never	Rarely	Sometimes	Usually	Always	DK	REF
PROMIS_SOCIAL_1 I have trouble doing all of my regular leisure activities with others	5	4	3	2	1	8	9
PROMIS_SOCIAL_2 I have trouble doing all of the family activities that I want to do	5	4	3	2	1	8	9
PROMIS_SOCIAL_3 I have trouble doing all of my usual work (include work at home)	5	4	3	2	1	8	9
PROMIS_SOCIAL_4 I have trouble doing all of the activities with friends that I want to do	5	4	3	2	1	8	9

Depression/Anxiety: 4-item PHQ4*HEAL CDE PHQ4*

These next questions are about your mood. Over the last 2 weeks, how often have you been bothered by the following problems?

6 Month Questionnaire – administered via phone or web

	Not at all	Several days	More than half of days	Nearly every day	DK	REF
PHQ_1 Feeling nervous, anxious or on edge	0	1	2	3	8	9
PHQ_2 Not being able to stop or control worrying	0	1	2	3	8	9
PHQ_3 Little interest or pleasure in doing things	0	1	2	3	8	9
PHQ_4 Feeling down, depressed, or hopeless	0	1	2	3	8	9

IF SITE=KPWA OR SUTTER, SKIP TO EUROQUOL

IF SUM(3,4)>=3 && SITE=IFH, SKIP TO PHQ4_CONS

IF SUM(3,4)>=3 && SITE=KPNC, SKIP TO PHQ4_EMAIL

PHQ4 CONS

PHONE:

It sounds like you have been feeling down [if possible, use a word patient used to describe their mood]. [pause for them to respond] I want to make sure you have support-- can I ask your provider to check in with you later today or tomorrow? They can hear more about how you're doing and offer some ideas for how you can feel better.

WEB:

Based on your answers to the last few questions, it sounds like you have been feeling down. We on the study team want to make sure you have support-- can we ask your provider to check in with you later today or tomorrow? They can hear more about how you're doing and offer some ideas for how you can feel better.

1	YES
0	NO

PHONE:

- IF **YES**: “Thanks, [pt name]. After our call, I’ll message your provider through the IFH study team. How would you feel about continuing with the survey? [allow option to reschedule]”
- IF **NO**: “OK [pt name], no problem. How would you feel about continuing with the survey? [allow option to reschedule]”

WEB:

- IF **YES**: “Thank you. After our call, your provider will be messaged through the IFH study team. Would you like to continue with the survey? [allow option to reschedule]”
- IF **NO**: “Thank you. Would you like to continue with the survey? [allow option to reschedule]”

PHQ4 EMAIL

[IFH] System send email to IFH PI, PM, and CRC (Raymond Teets RTeets@institute.org, Matt Beyrouty Mbeyrouty@institute.org, and Phoebe Rosenheim prosenheim@institute.org) with participant’s studyID, Score, CONS = 0 or 1.

[KPNC] System send email to Gabriela Sanchez (Gabriela.X.Sanchez@kp.org) and Andy Avins (Andy.L.Avins@kp.org) with participant’s studyID and Score.

*Health-Related Quality of Life for Economic Evaluation
EuroQuol-5D-5L*

EuroQuol-5D-5L phone version

We are trying to find out what you think about your health. I will explain what to do as I go along, but please interrupt me if you do not understand something or if things are not clear to you. There are no right or wrong answers. We are interested only in your personal view.

First, I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes your health TODAY.

Do not choose more than one answer in each group of questions.

EUROQUOL_1 First, I would like to ask you about mobility. Would you say that:

- 1 You have no problems walking?
- 2 You have slight problems walking?

- 3 You have moderate problems walking?
- 4 You have severe problems walking?
- 5 You are unable to walk?

EUROQUOL_2 Next, I would like to ask you about self-care. Would you say that:

- 1 You have no problems washing and dressing yourself?
- 2 You have slight problems washing and dressing yourself?
- 3 You have moderate problems washing and dressing yourself?
- 4 You have severe problems washing and dressing yourself?
- 5 You have unable to wash or dress yourself?

EUROQUOL_3 Next, I would like to ask you about usual activities, such as work, study, housework, family or leisure activities. Would you say that:

- ☐ 1 You have no problems doing your usual activities?
- ☐ 2 You have slight problems doing your usual activities?
- ☐ 3 You have moderate problems doing your usual activities?
- ☐ 4 You have severe problems doing your usual activities?
- ☐ 5 You are unable to do your usual activities?

EUROQUOL_4 Next, I would like to ask you about pain or discomfort. Would you say that:

- 1 You have no pain or discomfort?
- 2 You have slight pain or discomfort?
- 3 You have moderate pain or discomfort?
- 4 You have severe pain or discomfort?
- 5 You have extreme pain or discomfort?

EUROQUOL_5 Finally, I would like to ask you about anxiety or depression. Would you say that:

- 1 You are not anxious or depressed?
- 2 You are slightly anxious or depressed?
- 3 You are moderately anxious or depressed?
- 4 You are severely anxious or depressed?
- 5 You are extremely anxious or depressed?

EUROQUOL_HEALTH Now, I would like to ask you to say how good or bad your health is TODAY. I would like you to try to picture in your mind a scale that looks like a thermometer. The best health you can imagine is marked 100 (one hundred) at the top of the scale and the worst health you can imagine is marked 0 (zero) at the bottom. I would now like you to tell me the point on this scale where you would put your health TODAY.

ENTER R'S HEALTH TODAY: _____ (0-100)

998 DK
999 REF

EuroQuol-5D-5L web version

Note to SRP: Please show each question on a different screen and show the following text on the top of every page.

Please click the ONE box that best describes your health TODAY.

EUROQUOL_1

MOBILITY

- | | | |
|---|----------------------------------|--------------------------|
| 1 | I have no problems walking | ☐ |
| 2 | I have slight problems walking | ☐ |
| 3 | I have moderate problems walking | ☐ |
| 4 | I have severe problems walking | ☐ |
| 5 | I am unable to walk | ☐ |

EUROQUOL_2

SELF-CARE

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

EUROQUOL_3

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

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

EUROQUOL_4

PAIN / DISCOMFORT

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

EUROQUOL_5

ANXIETY / DEPRESSION

- | | | |
|---|------------------------------------|--------------------------|
| 1 | I am not anxious or depressed | ☐ |
| 2 | I am slightly anxious or depressed | ☐ |

- | | | |
|---|--------------------------------------|--------------------------|
| 3 | I am moderately anxious or depressed | ☐ |
| 4 | I am severely anxious or depressed | ☐ |
| 5 | I am extremely anxious or depressed | ☐ |

We would like to know how good or bad your health is TODAY. This scale is numbered from 0 to 100. 100 means the best health you can imagine. 0 means the worst health you can imagine. Please click on the scale to indicate how your health is TODAY.

Note to SRP: Please see EQ-5D self-complete document for image of 100-point scale. The blank below should auto-populate when the participant clicks on the scale.

Your health today: _____ (0-100)

COVID19

We would like to know a little more about how you have been affected by the COVID-19 (coronavirus) pandemic. Please remember that any information you share is kept confidential.

COVID_1 Over the past 3 months, how has the COVID-19 pandemic changed your access to healthcare, including pain treatment, prescription and over-the-counter medications, medical and mental health visits, other treatments?

- 2 Reduced your ability to get healthcare A LOT
- 1 Reduced your ability to get healthcare A LITTLE
- 0 NOT AFFECTED your ability to get healthcare.
- 1 IMPROVED your ability to get healthcare.
- 8 DK
- 9 REF

A. COVID_2 Over the past 3 months, how has the COVID-19 pandemic affected your overall health including physical, mental and emotional health including pain?

- 2 Your overall health is A LOT WORSE.
- 1 Your overall health is A LITTLE WORSE.
- 0 NOT AFFECTED your overall health. (SKIP to THANKS)
- 1 IMPROVED your overall health. (SKIP to THANKS)
- 8 DK (SKIP to THANKS)
- 9 REF (SKIP to THANKS)

- B. COVID_3 Please tell us a little more about how the COVID-19 pandemic has made your overall health [A LOT WORSE or A LITTLE WORSE; FILL RESPONSE FROM PREVIOUS Q]
-

COVID_4 In the past 3 months, have you had a diagnosis of COVID-19 confirmed by a COVID-19 test?

[IF NO] SKIP TO TKSEXIT

[IF YES] COVID_5 Did you have a hospital stay for COVID-19 during this time?

[DISCOVERY SEND EMAIL WITH STUDYID, STUDYARM, COVID_5 to Morgan.J.Fuoco@kp.org and Carolyn.m.eng@kp.org and KPWHRI---BackInAction@kp.org]

THANKREF

IF R ALREADY GAVE REFUSAL REASON; DO NOT NEED TO ASK

[IF DECLINING ONLY THIS INTERVIEW]: We will contact you for the 7-month check-in. Would you share your reasons for not wanting to do this interview?

RECORD PRIMARY REFUSAL REASON.

TKSEXIT

Thank you for being part of the Back in Action Study. We will contact you for the next check-in in about a month. Would you prefer to complete the check-in by web or phone?

1 Phone (SKIP TO PHONE)

2 Web (SKIP TO PHONE)

9 WANTS TO WITHDRAW FROM STUDY—COMPLETE STUDY WITHDRAWAL

SURVEY IN STUDY DATA GRID

THANKS

Thank you for your help today. We will contact you for a short check-in next month. Would you prefer to complete the check-in by web or by phone?

1 Phone

2 Web

9 WANTS TO WITHDRAW FROM STUDY—COMPLETE STUDY WITHDRAWAL
SURVEY IN STUDY DATA GRID

PHONE

What is the best number to reach you?

Home _____

Best number? [checkbox]

Mobile _____

Best number? [checkbox]

Work _____

Best number? [checkbox]

IF THANKS=2 OR TKSEXIT=2, SKP CONFIRM_EMAIL

CONTACT BESTTIME

What are the best times and days to reach you? [OPEN TEXT FIELD]

CONTACT NOTES

Is there anything else you'd like to share about the best way to reach you by phone? [OPEN TEXT FIELD]

SKP Questions

[IF EMAIL COLLECTED EARLIER:]

CONFIRM EMAIL

Great! Is this the email address you'd like to use? [SHOW EMAIL ADDRESS ON FILE]

1 YES [SKP Questions]

0 NO

[IF CONFIRM EMAIL = NO OR WE DO NOT HAVE ONE IN THE RECORD:]

Email1:

What email address would you like us to use? [OPEN TEXT WITH EMAIL FORMAT MASK]

Email2:

Please re-enter your email address. [OPEN TEXT WITH EMAIL FORMAT MASK]

[ADDRESSES WILL BE COMPARED FOR MATCH; IF THEY DO NOT, THERE WILL BE A PROMPT ASKING THAT THEY BE CHECKED AND CORRECTED]

CLINCARD

We will load \$25 on your ClinCard as a thank you for completing this survey. We will reload this card with money when you complete other surveys for the study. Even if you use up all the money on your card, please keep it for when we add more money to the card.

1	CONTINUE	SKIP TO QUESTIONS
2	LOST CLINCARD/NEEDS REPLACEMENT	[KPWA/KPNC/SH] SKIP TO ADDRESS CONFIRM [IFH] SKIP TO MAIL CLINCARD

MAIL CLINCARD

Would you like the new ClinCard mailed to you or would you like to pick it up in person at an IFH clinic?

[SHOW PPT ADDRESS ON RECORD]

2	PICK UP IN PERSON OR IF NO ADDRESS AVAILABLE	SKIP TO IFH PHONE, FILL MAILING ADDRESS AS IFH
1	MAILED AND ADDRESS SAME	SKIP TO QUESTIONS
0	MAILED AND UPDATE ADDRESS	SKIP TO NADDR

IFH PHONE

Please call the IFH study team at 1-929-237-9821 to coordinate a time for you to pick up your new ClinCard from the study team.

SKIP TO QUESTIONS

ADDRESS CONFIRM

Where shall we send the new ClinCard?

[SHOW PPT ADDRESS ON RECORD]

1	SAME ADDRESS	SKIP TO QUESTIONS
0	UPDATE ADDRESS	SKIP TO NADDR

NADDR

What is your new mailing address?

NEWADDR1	SPECIFY
NEWADDR2	SPECIFY
NEWCITY	SPECIFY
NEWSTATE	SPECIFY
NEWZIP	SPECIFY

[ALL SITES EXCEPT IFH] QUESTIONS

Do you have any questions? Please feel free to leave a voicemail at the study toll-free number at any time with questions. (IF NEEDED: The study toll-free number is 1-877-750-8159.)

[IFH] QUESTIONS

Do you have any questions? Please feel free to leave a voicemail at the study toll-free number at any time with questions. (IF NEEDED: The study toll-free number is 1-929-237-9821.)

1 END CONTACT

[IF MODE = WEB, SKIP WELCOME]

CONTACT

Hello. This is {INTNAME} calling from Kaiser Permanente Research Institute/{SITE} about the BackInAction acupuncture study.

May I please speak with {RESPONDENT}?

1	R AVAILABLE/ COMES TO PHONE	SKP CONFIRM
---	-----------------------------	-------------

IF RESPONDENT NOT AVAILABLE

Generally are mornings, afternoons or evenings the best time to reach {RESPONDENT}?

3	INFORMANT KNOWS R, BUT NOT AT THIS NUMBER	EXIT, CODE WRONG #
4	NO SUCH PERSON	VERIDIAL
7	GET GENERAL BT & SET CB	EXIT, SET CB
8	R REFUSES INT	SKP THANKREF
9	SOME OTHER PROBLEM	EXIT

CONFIRM

(Hello, this is {INTNAME} from Kaiser Permanente Research Institute/{SITE} calling about the BackInAction acupuncture study.)

I want to remind you that as an interviewer for the study I'm not supposed to know whether you were randomized to acupuncture or usual care in the study. Please try not to tell me whether or not you received acupuncture as part of the study.

I'm calling because you are due to complete your 12-month survey for the BackInAction Study. The survey will take about 50 minutes to complete. Is now still a good time?

1	YES	
7	NOT GOOD TIME, SET CB	EXIT, Set CB
8	REFUSES INTERVIEW	SKP THANKREF

RISKBENS

You will receive \$30 as a thank you for completing the survey.

I want to remind you that answering these questions is voluntary. You can skip any question you don't want to answer. Your decision to answer or not answer the questions will not affect your care at [site] in any way, and none of the information you provide will be shared with your doctor or added to your medical record. Okay, let's get started.

1	CONTINUE	
7	NOT GOOD TIME, SET CB	EXIT, Set CB
8	REFUSES INTERVIEW	SKP THANKREF

[IF MODE = PHONE SKIP TO ROLAND]

Web opening

Thank you for participating in the BackInAction research study! This survey should take about 50 minutes to complete. You will receive \$30 as a thank you for completing the survey.

Your participation is voluntary. You can skip any question you don't want to answer. Your decision to answer or not answer the questions will not affect your care at [site] in any way, and none of the information you provide will be shared with your doctor or added to your medical record.

[ALL SITES EXCEPT IFH] If you have any questions about the survey, please contact the study team at 1-877-750-8159.

[IFH] If you have any questions about the survey, please contact the study team at 1-929-237-9821.

Back pain related disability

ROLAND (all Roland items will be preceded by ROLAND)

When your back hurts, you may or may not find it difficult to do some of the things you normally do. The first questions include statements that people sometimes use to describe themselves when they have back pain. Please think of the past week. Answer "yes" if the statement describes you and "no" if it does not. In the past week...

1. Roland Morris Disability Questionnaire	NO	YES	DK	REF
--	-----------	------------	-----------	------------

12 Month Questionnaire – administered via phone or web

A. I stay at home most of the time because of the pain in my back.	0	1	8	9
B. I change position frequently to try and make my back comfortable.	0	1	8	9
C. I walk more slowly than usual because of the pain in my back.	0	1	8	9
D. Because of the pain in my back, I am not doing <u>any</u> of the jobs that I usually do around the house.	0	1	8	9
E. Because of the pain in my back, I use a handrail to get upstairs.	0	1	8	9
F. Because of the pain in my back, I lie down to rest more often.	0	1	8	9
G. Because of the pain in my back, I have to hold on to something to get out of a reclining chair.	0	1	8	9
H. Because of the pain in my back, I ask other people to do things for me.	0	1	8	9
I. I get dressed more slowly than usual because of the pain in my back.	0	1	8	9
J. I only stand up for short periods of time because of the pain in my back.	0	1	8	9
K. Because of the pain in my back, I try not to bend or kneel down.	0	1	8	9
L. I find it difficult to get out of a chair because of the pain in my back.	0	1	8	9

12 Month Questionnaire – administered via phone or web

M. My back hurts most of the time.	0	1	8	9
N. I find it difficult to turn over in bed because of the pain in my back.	0	1	8	9
O. My appetite is not very good because of the pain in my back.	0	1	8	9
P. I have trouble putting on my socks (or stockings) because of the pain in my back.	0	1	8	9
Q. I only walk short distances because of the pain in my back.	0	1	8	9
R. I sleep less well because of the pain in my back.	0	1	8	9
S. Because of the pain in my back, I get dressed with help from someone else.	0	1	8	9
T. I sit down for most of the day because of the pain in my back.	0	1	8	9
U. I avoid heavy jobs around the house because of the pain in my back.	0	1	8	9
V. Because of my back pain, I am more irritable and bad tempered with people.	0	1	8	9
W. Because of the pain in my back, I go upstairs more slowly than usual.	0	1	8	9
X. I stay in bed most of the time because of the pain in my back.	0	1	8	9

Pain intensity and pain interference

PEG

The next few questions ask you to describe your lower back pain in the past week and how it may or may not interfere with your normal activities.

[PHONE] PEG_PAIN

What number best describes your pain on average in the past week, using a 0 to 10 scale where 0 is **no pain** and 10 is **pain as bad as you can imagine**? _____

8 DK
9 REF

[ONLINE] PEG_PAIN

On a scale of 0 to 10 where 0 is no pain and 10 is pain as bad as you can imagine, what number best describes your pain on average in the past week?

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

[PHONE] PEG_INTERFERE

What number best describes how, in the past week, pain interfered with your enjoyment of life using a 0 to 10 scale where 0 is **does not interfere** and 10 is **completely interferes**?

89 DK
99 REF

[ONLINE] PEG_INTERFERE

On a scale of 0 to 10 where 0 does not interfere and 10 completely interferes, what number best describes how, in the past week, pain interfered with your enjoyment of life?

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

[PHONE] PEG_OFTEN

What number best describes how, in the past week, pain interfered with your general activity using a 0 to 10 scale where 0 is **does not interfere** and 10 is **completely interferes**?

89 DK
99 REF

[ONLINE] PEG_OFTEN

On a scale of 0 to 10 where 0 does not interfere and 10 completely interferes, what number best describes how, in the past week, pain interfered with your general activity?

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Back Pain-Related healthcare services

These next questions are about your use of health services, products, and self-care practices to manage low back pain in in the **past month**.

TX_[FOLLOWED BY NAME INDICATED FOR EACH TX TYPE]

Have you used...[FILL TEXT FOR EACH]

- 1 Yes
- 0 No (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
- 8 DK (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
- 9 REF (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).

TX_[tx type]_LBP

Have you used this product for back pain or for other needs?

- 1 Yes, for back pain
- 2 Yes, but for other needs
- 8 DK
- 9 REF

NSAIDS

Nonsteroidal anti-inflammatory drugs (NSAIDs) such as: Advil, Aleve, aspirin, Ibuprofen, Motrin, Naprosyn, naproxen, Voltaren

ACETA

Acetaminophen medications such as: Tylenol

CANNABIS

Cannabis / Marijuana (including THC/CBD combination products)

OTHER_CBD

Other CBD only products

HERBAL

Herbs or nutritional supplements not including vitamins

We are now going to ask you about exercise and movement. We are interested in your **typical** patterns of exercise over the past month.

ACTIVE EXERCISE

During the past month, how often have you **exercised actively**, for example walking, cycling, swimming, jogging or active sports?

- 0 Not at all (SKIP TO **BACK EXERCISE**)
- 1 Less than once a week (SKIP TO **BACK EXERCISE**)
- 2 At least weekly (CONTINUE to **ACTIVE DAYS**)
- 8 DK [SKIP TO **BACK EXERCISE**]
- 9 REF [SKIP TO **BACK EXERCISE**]

ACTIVE DAYS

During the past month, in a typical week, how many days have you exercised actively?

_____ Days (0-7 days)

- 8 DK
- 9 REF

ACTIVE TIME

During the past month, on the days when you have exercised actively, how long have you exercised?

_____ Hours (0-8) _____ Minutes (1-120 minutes) [AVERAGE
TIME IF DIFFERS BETWEEN DAYS]

- 998 DK
- 999 REF

BACK EXERCISE

During the past month, how often have you done **low back exercises**?

- 0 Not at all (SKIP TO **MOVEMENT**)
- 1 Less than once a week (SKIP TO **MOVEMENT**)
- 2 At least weekly (CONTINUE to **BACK_DAYS**)
- 8 DK [SKIP TO **MOVEMENT**]
- 9 REF [SKIP TO **MOVEMENT**]

BACK_DAYS During the past month, in a typical week, how many days have you done low back exercises?

_____ Days (0-7 days)

- 8 DK
- 9 REF

BACK_TIME During the past month, on the days when you have done back exercises, how long have you exercised?

_____ Hours (0-8) _____ Minutes (1-120 minutes) [AVERAGE
TIME IF DIFFERS BETWEEN DAYS]

- 998 DK
- 999 REF

MOVEMENT

During the past month, how often have you engaged in **other movement-based therapies such as dance, Tai chi or yoga?**

- 0 Not at all (SKIP TO **TX_SELF-MGMT**)
- 1 Less than once a week (SKIP TO **TX_SELF-MGMT**)
- 2 At least weekly (CONTINUE to **MOVEMENT_DAYS**)
- 8 DK (SKIP TO **TX_SELF-MGMT**)
- 9 REF (SKIP TO **TX_SELF-MGMT**)

MOVEMENT_DAYS

During the past month, in a typical week, how many days have you engaged in other movement-based therapies?

_____ Days (0-7 days)

- 8 DK
- 9 REF

MOVEMENT_TIME

During the past month, on the days when you have engaged in other movement-based therapies, how long have you spent doing these therapies?

_____ Hours (0-8) _____ Minutes (1-120 minutes) [AVERAGE
TIME IF DIFFERS BETWEEN DAYS]
998 DK
999 REF

The next questions are about your use of programs or services for pain management for your low back pain in the **past month**.

Have you used...[FILL TEXT FOR EACH]

- 1 Yes
- 0 No (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
- 8 DK (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).
- 9 REF (SKP TO NEXT SERVICE/PRODUCT/PRACTICE).

TX_[tx type]_LBP

Have you used this program for back pain or for other needs?

- 1 Yes, for back pain
- 2 Yes, but for other needs
- 8 DK
- 9 REF

TX SELF-MGMT A structured self-management class or program led by a healthcare provider for pain, stress management, or something you might expect might help with pain management (such as mindfulness, meditation, pain education).

TX MIND BODY Mind-body techniques such as relaxed breathing, guided imagery, or progressive muscle relaxation on your own

TX ONLINE Online self-paced programs to manage pain [if NO, skip to TX_COUNSEL]

TX ONLINE NAME What is the name of the program(s) you used to manage pain?

TX COUNSEL Psychological counseling such as cognitive-behavioral therapy (either in person or by telephone or video visit)

Patient Global Impression of Change (PGIC)

For the next two questions please choose the answer that best describes your experience.

PGIC 1

Since the start of the study, my overall pain is

- 6 Much better
- 5 Moderately better
- 4 A little better
- 3 No change
- 2 A little worse
- 1 Moderately worse
- 0 Much worse
- 8 DK
- 9 REF

PGIC 2

Since the start of the study, how I am doing overall is

- 6 Much better
- 5 Moderately better
- 4 A little better
- 3 No change
- 2 A little worse
- 1 Moderately worse
- 0 Much worse
- 8 DK
- 9 REF

HEAL CDE Sleep duration

Sleep Duration Question

PROMIS Sleep Disturbance 6a

The next set of questions ask about your sleep patterns.

During the past month, about how many hours and minutes of actual sleep did you get each night? (This may be different than the number of hours and minutes you spent in bed).

SLEEP_H_HOURS____hours (0-15 hours) and SLEEP_M_MINUTES____minutes (0-59 minutes) of sleep per night

SLEEP_DK DK

SLEEP_REF REF

Fatigue

4-item PROMIS Fatigue measure (part of PROMIS® -29)

Next are some questions about your energy level and fatigue in the past week. In the past week, would you say...

	Not at all	A little bit	Somewhat	Quite a bit	Very much	DK	REF
PROMIS_FATIGUE_1 I feel fatigued	1	2	3	4	5	8	9
PROMIS_FATIGUE_2 I have trouble <u>starting</u> things because I am tired	1	2	3	4	5	8	9
PROMIS_FATIGUE_3 How run-down did you feel on average?	1	2	3	4	5	8	9
PROMIS_FATIGUE_4 How fatigued were you on average?	1	2	3	4	5	8	9

Physical functioning

PROMIS Physical Functioning Short Form 6b (part of PROMIS®-29)

For these next questions, please think of how your health may limit your physical activities. Even if you choose not to regularly engage in these activities, please answer if you **are able** to do the following...

12 Month Questionnaire – administered via phone or web

	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do	DK	REF
PROMIS_SF6B_1 Are you able to do chores such as vacuuming or yard work?	5	4	3	2	1	8	9
PROMIS_SF6B_2 Are you able to go up and down stairs at a normal pace?	5	4	3	2	1	8	9
PROMIS_SF6B_3 Are you able to go for a walk of at least 15 minutes?	5	4	3	2	1	8	9
PROMIS_SF6B_4 Are you able to run errands and shop?	5	4	3	2	1	8	9

[PHONE] The answer choices for the next two questions are a little different.

	Not at all	Very little	Somewhat	Quite a lot	Cannot do	DK	REF
PROMIS_SF6B_5 Does your health now limit you in doing two hours of physical labor?	5	4	3	2	1	8	9
PROMIS_SF6B_6 Does your health now limit you in doing moderate work around the house like vacuuming, sweeping floors or carrying groceries?	5	4	3	2	1	8	9

PROMIS Social role functioning*PROMIS Ability to Participate in Social Roles 4A*

Even if you choose not to regularly engage in these activities, please answer how often you **have trouble** doing the following...

	Never	Rarely	Sometimes	Usually	Always	DK	REF
PROMIS_SOCIAL_1 I have trouble doing all of my regular leisure activities with others	5	4	3	2	1	8	9
PROMIS_SOCIAL_2 I have trouble doing all of the family activities that I want to do	5	4	3	2	1	8	9
PROMIS_SOCIAL_3 I have trouble doing all of my usual work (include work at home)	5	4	3	2	1	8	9
PROMIS_SOCIAL_4 I have trouble doing all of the activities with friends that I want to do	5	4	3	2	1	8	9

Depression/Anxiety: 4-item PHQ4*HEAL CDE PHQ4*

These next questions are about your mood. Over the last 2 weeks, how often have you been bothered by the following problems?

12 Month Questionnaire – administered via phone or web

	Not at all	Several days	More than half of days	Nearly every day	DK	REF
PHQ_1 Feeling nervous, anxious or on edge	0	1	2	3	8	9
PHQ_2 Not being able to stop or control worrying	0	1	2	3	8	9
PHQ_3 Little interest or pleasure in doing things	0	1	2	3	8	9
PHQ_4 Feeling down, depressed, or hopeless	0	1	2	3	8	9

IF SITE=KPWA OR SUTTER, SKIP TO EUROQUOL

IF SUM(3,4)>=3 && SITE=IFH, SKIP TO PHQ4_CONS

IF SUM(3,4)>=3 && SITE=KPNC, SKIP TO PHQ4_EMAIL

PHQ4 CONS

PHONE:

It sounds like you have been feeling down [if possible, use a word patient used to describe their mood]. [pause for them to respond] I want to make sure you have support-- can I ask your provider to check in with you later today or tomorrow? They can hear more about how you're doing and offer some ideas for how you can feel better.

WEB:

Based on your answers to the last few questions, it sounds like you have been feeling down. We on the study team want to make sure you have support-- can we ask your provider to check in with you later today or tomorrow? They can hear more about how you're doing and offer some ideas for how you can feel better.

1	YES
0	NO

PHONE:

12 Month Questionnaire – administered via phone or web

- IF **YES**: “Thanks, [pt name]. After our call, I’ll message your provider through the IFH study team. How would you feel about continuing with the survey? [allow option to reschedule]”
- IF **NO**: “OK [pt name], no problem. How would you feel about continuing with the survey? [allow option to reschedule]”

WEB:

- IF **YES**: “Thank you. After our call, your provider will be messaged through the IFH study team. Would you like to continue with the survey? [allow option to reschedule]”
- IF **NO**: “Thank you. Would you like to continue with the survey? [allow option to reschedule]”

PHQ4 EMAIL

[IFH] System send email to IFH PI, PM, and CRC (Raymond Teets RTeets@institute.org, Matt Beyrouty Mbeyrouty@institute.org, and Phoebe Rosenheim prosenheim@institute.org) with participant’s studyID, Score, CONS = 0 or 1.

[KPNC] System send email to Gabriela Sanchez (Gabriela.X.Sanchez@kp.org) and Andy Avins (Andy.L.Avins@kp.org) with participant’s studyID and Score.

Health-Related Quality of Life for Economic Evaluation *EuroQuol-5D-5L*

EuroQuol-5D-5L phone version

We are trying to find out what you think about your health. I will explain what to do as I go along, but please interrupt me if you do not understand something or if things are not clear to you. There are no right or wrong answers. We are interested only in your personal view.

First, I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes your health TODAY.

Do not choose more than one answer in each group of questions.

EUROQUOL_1 First, I would like to ask you about mobility. Would you say that:

- 1 You have no problems walking?
- 2 You have slight problems walking?

- 3 You have moderate problems walking?
- 4 You have severe problems walking?
- 5 You are unable to walk?

EUROQUOL_2 Next, I would like to ask you about self-care. Would you say that:

- 1 You have no problems washing and dressing yourself?
- 2 You have slight problems washing and dressing yourself?
- 3 You have moderate problems washing and dressing yourself?
- 4 You have severe problems washing and dressing yourself?
- 5 You have unable to wash or dress yourself?

EUROQUOL_3 Next, I would like to ask you about usual activities, such as work, study, housework, family or leisure activities. Would you say that:

- ☐ 1 You have no problems doing your usual activities?
- ☐ 2 You have slight problems doing your usual activities?
- ☐ 3 You have moderate problems doing your usual activities?
- ☐ 4 You have severe problems doing your usual activities?
- ☐ 5 You are unable to do your usual activities?

EUROQUOL_4 Next, I would like to ask you about pain or discomfort. Would you say that:

- 1 You have no pain or discomfort?
- 2 You have slight pain or discomfort?
- 3 You have moderate pain or discomfort?
- 4 You have severe pain or discomfort?
- 5 You have extreme pain or discomfort?

EUROQUOL_5 Finally, I would like to ask you about anxiety or depression. Would you say that:

- 1 You are not anxious or depressed?
- 2 You are slightly anxious or depressed?
- 3 You are moderately anxious or depressed?
- 4 You are severely anxious or depressed?
- 5 You are extremely anxious or depressed?

EUROQUOL_HEALTH Now, I would like to ask you to say how good or bad your health is TODAY. I would like you to try to picture in your mind a scale that looks like a thermometer. The best health you can imagine is marked 100 (one hundred) at the top of the scale and the worst health you can imagine is marked 0 (zero) at the bottom. I would now like you to tell me the point on this scale where you would put your health TODAY.

ENTER R'S HEALTH TODAY: _____ (0-100)

998 DK

999 REF

EuroQuol-5D-5L web version

Note to SRP: Please show each question on a different screen and show the following text on the top of every page.

Please click the ONE box that best describes your health TODAY.

EUROQUOL_1

MOBILITY

- | | | |
|---|----------------------------------|--------------------------|
| 1 | I have no problems walking | ☐ |
| 2 | I have slight problems walking | ☐ |
| 3 | I have moderate problems walking | ☐ |
| 4 | I have severe problems walking | ☐ |
| 5 | I am unable to walk | ☐ |

EUROQUOL_2

SELF-CARE

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

EUROQUOL_3

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

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

EUROQUOL_4

PAIN / DISCOMFORT

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

EUROQUOL_5

ANXIETY / DEPRESSION

- | | | |
|---|------------------------------------|--------------------------|
| 1 | I am not anxious or depressed | ☐ |
| 2 | I am slightly anxious or depressed | ☐ |

12 Month Questionnaire – administered via phone or web

- | | | |
|---|--------------------------------------|--------------------------|
| 3 | I am moderately anxious or depressed | ☐ |
| 4 | I am severely anxious or depressed | ☐ |
| 5 | I am extremely anxious or depressed | ☐ |

We would like to know how good or bad your health is TODAY. This scale is numbered from 0 to 100. 100 means the best health you can imagine. 0 means the worst health you can imagine. Please click on the scale to indicate how your health is TODAY.

Note to SRP: Please see EQ-5D self-complete document for image of 100-point scale. The blank below should auto-populate when the participant clicks on the scale.

Your health today: _____ (0-100)

Use of Acupuncture

These next few questions are about your use of acupuncture during the past 12 months when you were enrolled in the BackInAction study.

ACU_1

In the year since you enrolled in the study on [RANDO_DATE], did you receive any acupuncture treatments that were not part of the study?

- 1 YES
- 0 NO [SKIP TO COVID_1]
- 8 DK [SKIP TO COVID_1]
- 9 REF [SKIP TO COVID_1]

ACU_2

How many acupuncture treatments that were not part of the study did you receive during the year since you enrolled in the study?

- Five or fewer
- Between 6 and 12
- More than 12
- 98 DK [SKIP TO ACU_3]
- 99 REF [SKIP TO ACU_3]

ACU_3

How many acupuncture treatments that were not part of the study did you receive during your first three months in the study, about [RANDO_DATE] to [RANDO_DATE+90]?

- Five or fewer
- Between 6 and 12
- More than 12
- 98 DK [SKIP TO ACU_4]
- 99 REF [SKIP TO ACU_4]

ACU_4

How many acupuncture treatments that were not part of the study did you receive during the next three months in the study, about [RANDO_DATE+90] to [RANDO_DATE+180]?

Five or fewer

Between 6 and 12

More than 12

98 DK [SKIP TO ACU_5]

99 REF [SKIP TO ACU_5]

ACU_5

How many acupuncture treatments that were not part of the study did you receive during the past six months [RANDO_DATE+180] to today?

Five or fewer

Between 6 and 12

More than 12

8 DK

9 REF

COVID19

We would like to know a little more about how you have been affected by the COVID-19 (coronavirus) pandemic. Please remember that any information you share is kept confidential.

COVID_1 Over the past 6 months, how has the COVID-19 pandemic changed your access to healthcare, including pain treatment, prescription and over-the-counter medications, medical and mental health visits, other treatments?

-2 Reduced your ability to get healthcare A LOT

-1 Reduced your ability to get healthcare A LITTLE

0 NOT AFFECTED your ability to get healthcare.

1 IMPROVED your ability to get healthcare.

8 DK

9 REF

A. COVID_2 Over the past 6 months, how has the coronavirus pandemic affected your overall health including physical, mental and emotional health including pain?

-2 Your overall health is A LOT WORSE.

-1 Your overall health is A LITTLE WORSE.

0 NOT AFFECTED your overall health. (SKIP to THANKS)

1 IMPROVED your overall health. (SKIP to THANKS)

- 8 DK (SKIP to THANKS)
- 9 REF (SKIP to THANKS)

B. COVID_3 Please tell us a little more about how the COVID-19 pandemic has made your overall health [A LOT WORSE or A LITTLE WORSE; FILL RESPONSE FROM PREVIOUS Q]_____

COVID_4 In the past 6 months, have you had a diagnosis of COVID-19 confirmed by a COVID-19 test?

[IF NO] SKIP TO TKSEXIT

[IF YES] COVID_5 Did you have a hospital stay for COVID-19 during this time?

[DISCOVERY SEND EMAIL WITH STUDYID, STUDYARM, COVID_5 to

Morgan.J.Fuoco@kp.org and Carolyn.m.eng@kp.org and KPWHRI---

BackInAction@kp.org]_____

Tobacco, Alcohol, Prescription medications, and other Substance (TAPS)

HEAL CDE TAPS

The next few questions are about your tobacco and other substance use in the in the past year.

TOBACCO

In the PAST 12 MONTHS, how often have you used any tobacco product-- for example, cigarettes, e-cigarettes, cigars, pipes, or smokeless tobacco?

- 0 - Daily or Almost Daily
- 1 - Weekly
- 2 - Monthly
- 3 - Less Than Monthly
- 4 – Never
- 8 DK
- 9 REF

BINGE

In the PAST 12 MONTHS, how often have you had 5 (IF SEX_BIRTH = 1 (**MALE**) : **5**; IF SEX_BIRTH > 1 (**FEMALE/INTER/UNK/DK/REF**): **4**) or more drinks containing alcohol in one day? One standard drink is about 1 small glass of wine (5 oz), 1 beer (12 oz), or 1 single shot of liquor.

- 0 - Daily or Almost Daily
- 1 - Weekly

- 2 - Monthly
- 3 - Less Than Monthly
- 4 - Never
- 8 DK
- 9 REF

DRUGS

In the PAST 12 MONTHS, how often have you used any drugs including marijuana, cocaine or crack, heroin, methamphetamine or crystal meth, hallucinogens, ecstasy/MDMA?

- 0 - Daily or Almost Daily
- 1 - Weekly
- 2 - Monthly
- 3 - Less Than Monthly
- 4 – Never
- 8 DK
- 9 REF

RX_MISUSE

In the PAST 12 MONTHS, how often have you used any prescription medications just for the feeling, more than prescribed or that were not prescribed for you? Prescription medications that may be used this way include:

- Opiate pain relievers (for example, OxyContin, Vicodin, Percocet, Methadone)
- Medications for anxiety or sleeping (for example, Xanax, Ativan, Klonopin)
- Medications for ADHD (for example, Adderall or Ritalin)

- 0 – Daily or Almost Daily
- 1 – Weekly
- 2 – Monthly
- 3 – Less Than Monthly
- 4 – Never
- 8 DK
- 9 REF

THANKREF

IF R ALREADY GAVE REFUSAL REASON; DO NOT NEED TO ASK

[IF DECLINING ONLY THIS INTERVIEW]: Would you share your reasons for not wanting to do this interview?

RECORD PRIMARY REASON.

1	NOT INTERESTED/DON'T WANT TO PARTICIPATE
2	DOES NOT HAVE TIME
3	INTERVIEW TOO LONG
11	DEALING WITH OTHER HEALTH OR LIFE ISSUES
9	PRIVACY CONCERNS
16	NO REASON GIVEN AND/OR HUNG UP
15	OTHER (PLEASE SPECIFY)
17	WANTS TO WITHDRAW FROM INTERVENTION— COMPLETE INTERVENTION WITHDRAWAL SURVEY IN STUDY DATA GRID
18	WANTS TO WITHDRAW FROM STUDY—COMPLETE STUDY WITHDRAWAL SURVEY IN STUDY DATA GRID

TKSEXIT

This is the final study interview. Thank you for being part of the Back in Action Study!
SKP QUESTIONS

THANKS

Thank you for your help today. This is the last survey for the BackInAction study. We appreciate you being a part of the study!

CLINCARD

We will load \$30 on your ClinCard as a thank you for completing this survey.

<u>1</u>	CONTINUE	SKIP TO QUESTIONS
<u>2</u>	LOST CLINCARD/NEEDS REPLACEMENT	[KPWA/KPNC/SH] SKIP TO ADDRESS CONFIRM

		[IFH] SKIP TO MAIL_CLINCARD
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MAIL_CLINCARD

Would you like the new ClinCard mailed to you or would you like to pick it up in person at an IFH clinic?

[SHOW PPT ADDRESS ON RECORD]

<u>2</u>	PICK UP IN PERSON OR IF NO ADDRESS AVAILABLE	SKIP TO IFH_PHONE, FILL MAILING ADDRESS AS IFH
<u>1</u>	MAILED AND ADDRESS SAME	SKIP TO QUESTIONS
<u>0</u>	MAILED AND UPDATE ADDRESS	SKIP TO NADDR

IFH_PHONE

Please call the IFH study team at 1-929-237-9821 to coordinate a time for you to pick up your new ClinCard from the study team.

SKIP TO QUESTIONS

ADDRESS_CONFIRM

Where shall we send the new ClinCard?

[SHOW PPT ADDRESS ON RECORD]

<u>1</u>	SAME ADDRESS	SKIP TO QUESTIONS
<u>0</u>	UPDATE ADDRESS	SKIP TO NADDR

NADDR

What is your new mailing address? NEWADDR1	SPECIFY
NEWADDR2	SPECIFY
NEWCITY	SPECIFY
NEWSTATE	SPECIFY
NEWZIP	SPECIFY

[ALL SITES EXCEPT IFH] QUESTIONS

Do you have any questions? Please feel free to leave a voicemail at the study toll-free number at any time with questions. (IF NEEDED: The study toll-free number is 1-877-750-8159.)

[IFH] QUESTIONS

Do you have any questions? Please feel free to leave a voicemail at the study toll-free number at any time with questions. (IF NEEDED: The study toll-free number is 1-929-237-9821.)

1 END CONTACT