

17795

COSMOS 2

Birth date: / / → Your social security number (for identification purposes ONLY) - -

What is your sex? Male Female

First, a few questions about your health history:

- 1. Have you ever been diagnosed with skin cancer? No Yes
 IF YES, please specify type: Melanoma Other skin cancer (e.g., basal cell, squamous cell) Not sure
 Was any skin cancer diagnosed within the past 2 years? No Yes
- 2. OTHER THAN skin cancer, have you ever been diagnosed with another type of cancer (e.g. breast, lung, prostate, colon, or other type of cancer)? No Yes
 IF YES, please specify type(s) other than skin cancer: _____
 Was any cancer diagnosed within the past 2 years? No Yes
- 3. Have you ever had a heart attack or a stroke? No Yes
- 4. Have you ever had coronary bypass surgery (CABG) OR a coronary angioplasty (PTCA, when a balloon is used to open a blockage in an artery) OR a stent? No Yes

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The next several questions ask about your use of nutritional supplements. A supplement is a product, often in the form of a pill, which provides vitamins, minerals, or fatty acids.

- 5. Do you regularly take a COCOA EXTRACT supplement (pills, capsules or powder)? No Yes
 IF YES: Are you willing to stop taking these supplements in order to participate in this trial? (You will NOT have to restrict intake of chocolate, hot chocolate or mocha beverages.) No Yes
- 6. Do you regularly take a MULTIVITAMIN supplement? No Yes
 IF YES: Are you willing to stop taking a multivitamin supplement in order to participate in this trial? (You will be allowed to take up to 1,200 mg of calcium and /or up to 1,000 IU of vitamin D supplements.) No Yes
- 7. NOT including your diet, how much TOTAL calcium do you take each day from nutritional supplements such as single tablets of calcium, multivitamins, or Os-Cal, Citracal, Calcium+D, VIACTIV, or Tums? Referring to package labels, please add up ALL your non-diet sources of calcium.
 None 500 mg or less/day 501-1,200 mg/day 1,201-1,500 mg/day Greater than 1,500 mg/day
- 8. Are you willing to limit your TOTAL intake of calcium from nutritional supplements to 1,200 mg or less per day in order to participate in this trial? No Yes
- 9. NOT including your diet, how much TOTAL vitamin D do you take each day from nutritional supplements such as single tablets of vitamin D, multivitamins, calcium supplements (Calcium+D) or drugs that may include vitamin D (Example: Fosamax+D)? Referring to package labels, please add up ALL your non-diet sources of vitamin D.
 None 400 IU or less/day 401-800 IU/day 801-1,000 IU/day greater than 1,000 IU/day
- 10. Are you willing to limit your TOTAL intake of vitamin D from nutritional supplements to 1,000 IU or less per day in order to participate in this trial? No Yes
- 11. The cocoa extract contains a very small amount of caffeine (less than the amount in 1/5 cup of coffee). Do you have extreme sensitivity to caffeine that would prevent you from taking a cocoa extract supplement?
 No Yes

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12. How tall are you without your shoes on?

	AND		
feet		inches	

13. How much do you weigh without your shoes on?

pounds		

14. In the PAST 2 YEARS, did you lose five (5) or more pounds at any time? No Yes

IF YES, was this weight loss on purpose? No Yes

15. Have you EVER had your blood glucose (fasting or non-fasting) or hemoglobin A1c measured?

No Yes

IF YES, how many years ago was your most recent blood glucose or hemoglobin A1c test?

Less than 1 year ago 1-2 years ago 3-5 years ago More than 5 years ago Don't know

16. Have you EVER been diagnosed with diabetes? (Women only: other than diabetes when you were pregnant.) No Yes

IF YES:

a. When were you diagnosed with diabetes?

Less than 1 year ago 1-2 yrs. ago 3-5 yrs. ago 6-10 yrs. ago More than 10 yrs. ago

b. Were you diagnosed with diabetes before age 30? No Yes

c. How is your diabetes currently being treated? (mark all that apply)

Diet Exercise Insulin injections Non-insulin injections (Ex: Exenatide, Byetta, Bydureon, Victoza, Symlin)
 Metformin/Glucophage Other oral glucose-lowering pills Don't know

17. When was your last eye exam?

Less than 1 year ago 1-2 yrs. ago 3-5 yrs. ago More than 5 yrs. ago Never had an eye exam

18. Have you EVER had macular degeneration? No Yes

19. The following questions are about sleep, pain, and stress in the past 7 days.

In the past 7 days...	Not at all	A little bit	Somewhat	Quite a bit	Very much
My sleep was refreshing.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I had a problem with my sleep.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I had difficulty falling asleep.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel fatigued.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I have trouble starting things because I am tired.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much did pain interfere with your day to day activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How run-down did you feel on average?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

In the past 7 days...	Never	Rarely	Sometimes	Often	Always
I felt fearful.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I found it hard to focus on anything other than my anxiety.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My worries overwhelmed me.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt uneasy.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

The following questions have to do with blood pressure:

20. Has a physician EVER told you that you have high blood pressure? No Yes Don't know
21. Have you EVER taken prescription medication to control high blood pressure? No Yes Don't know
 IF YES: Are you currently taking any prescription medication(s) to control high blood pressure? No Yes

22. Are you CURRENTLY taking any of the following prescription medications?
 Mark one answer for each row

	Taking for high blood pressure	Taking for other reasons, or not sure	Not currently taking this medication
a. Beta-blockers (Ex: atenolol, metoprolol)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Calcium channel blockers (Ex: amlodipine, diltiazem)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Diuretics (Ex: hydrochlorothiazide, furosemide)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. ACE inhibitors (Ex: lisinopril, enalapril)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Angiotensin receptor blockers (Ex: losartan, irbesartan)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Aldosterone receptor blockers (Ex: spironolactone, eplerenone)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Alpha-blockers (Ex: terazosin, doxazosin)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

23. How many years ago was your most recent blood pressure measurement?

Less than 1 year ago 1-2 years ago 3-5 years ago More than 5 years ago Don't know

24. Blood pressure is represented as two numbers, an UPPER NUMBER (systolic) and a LOWER NUMBER (diastolic). For example, a systolic blood pressure of 110 and diastolic blood pressure of 70 is written as 110/70.

Do you know your most recent blood pressure measurement? No Yes

IF YES: Please mark the bubbles below that best match your most recent blood pressure measurement. Mark only one bubble for UPPER and one bubble for LOWER.

UPPER BLOOD PRESSURE NUMBER (systolic):

- less than 110 130-139 160-169
 110-119 140-149 170-179
 120-129 150-159 180 or higher

LOWER BLOOD PRESSURE NUMBER (diastolic):

- less than 65 75-79 90-94
 65-69 80-84 95-99
 70-74 85-89 100 or higher

25. How many years ago was your most recent blood cholesterol test?

Less than 1 year ago 1-2 years ago 3-5 years ago More than 5 years ago Don't know

26. The level of total cholesterol in the blood is given as one number, usually 3-digits in length. Do you know your most recent total cholesterol level?

No Yes →

IF YES: Please mark the bubble below that best matches your most recent total cholesterol level. Mark only one bubble.

- less than 140 140-159 160-179 180-199 200-219 220-239
 240-259 260-279 280-299 300-319 320 or higher

27. In the PAST YEAR, have you been hospitalized for heart failure or congestive heart failure? No Yes

IF YES, how many times in the past year? 1 2 3 or more

28. In the PAST YEAR, have you been treated in the emergency room (but not hospitalized) for heart failure or congestive heart failure? No Yes

IF YES, how many times in the past year? 1 2 3 or more



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29. As a participant in the COSMOS trial, you may have an opportunity to participate in other smaller studies, called sub-studies, that are related to the supplements that we are studying (cocoa extract and multivitamins).

Would you be willing to learn about additional sub-studies? (One example of a sub-study would be about memory.)

- No
 Yes
 Not sure

30. An additional valuable part of the COSMOS trial is to look at amounts of cocoa flavanols (found in cocoa extract), nutrients (found in a multivitamin), and other factors (biomarkers) in blood samples provided by participants. The blood samples for this trial would be drawn at a later date by a health care professional.

Would you be willing to have a blood sample drawn as part of the COSMOS trial? (You can still take part in the COSMOS trial if you prefer not to have a blood draw).

- No
 Yes
 Not sure

In the event that we need to reach you to clarify any of your responses, please provide your contact information here.

HOME PHONE () -

CELL PHONE () -

WORK PHONE () -

What is your preferred method of contact?

Home phone Cell phone
 Work phone No difference

→ **E-MAIL ADDRESS:** _____

Thank you!

Please check that you answered each question. Then, place your completed form and your signed consent (only the back page of the consent form) in the enclosed pre-paid envelope.