

# Pre-Screening (Interviewer Administered) Version 5

PID: 0	Acrostic: 0	Visit:
Completed: d_form	Date Form	Administration Type: admin
Reviewed by: compby	Language: language	

### Pre-Screening Information

1. Has anyone interviewed you about the study before?

psbefore

1 Yes  
 2 No

→ If Yes,

When? psd\_when  (Month/Day/Year)

What was the outcome? psoutcme

2 Where did you most recently hear about the Look AHEAD study?  
(Check only one.)

psradio value="1"  1. Radio  
For staff use only: psrdtpe

psstv value="1"  2. Television  
For staff use only: pstvtpe

psart value="1"  3. Article in newspaper or magazine  
psad value="1"  4. Advertisement in newspaper or magazine  
psbroch value="1"  5. Brochure  
For staff use only:  
How did you obtain the brochure? psbrtpe

- 1 Mailed
- 2 Display
- 3 Work site

**pshfair** value="1"  6. Health fair or screening event

**For staff use only:**

Where was it? **psfair\_sp**

**psweb** value="1"  7. Web site

**pspost** value="1"  8. Poster/flyer

**psphys** value="1"  9. Physician or other health professional

**For staff use only:** **psdoc**

- 1 Community
- 2 Study staff

**psfrnd** value="1"  10. Friend or relative

**psoth** value="1"  11. Other, specify

**For staff use only:**

Specify: **psoth\_sp**

**psdr1** value="1"  12. Don't remember

### Pre-Screening Information - continued

3. How old are you?

**psage**  years old

4. Date of birth has been moved to Eligibility Form A.

**For staff use only:** **psage45**

- 1 Less than 45 years old
- 2 Over 75 years old

5. Male or Female

**psgender**

- 1 Male
- 2 Female

6. Are you Latino, Hispanic, or of Spanish origin?

**pshisp**

- 1 Yes
- 2 No

→ Please continue with question 7

7. Which of the following best describes you? (You may check more than one.)

African American/Black

American Indian/Native American/Alaskan Native

Specify

Asian/Pacific Islander

Specify

White

Other

Specify

### Pre-Screening Information - continued

Have you "ever" had any of the following?

7a. Heart attack

**pscvda**

1 Yes  
2 No

→ If "Yes", in past 3 months?

**pshtatt**

1 Yes  
2 No

**If "Yes", Rescreen**

7b. Stroke, ministroke or TIA

**pscvdb**

1 Yes  
2 No

→ If "Yes", in past 3 months?

**psstroke**

1 Yes  
2 No

**If "Yes", Rescreen**

7c. Heart Bypass Surgery

pscvc

- 1 Yes
- 2 No

→ If "Yes", in past 3 months?

psbypass

- 1 Yes
- 2 No

If "Yes", Rescreen

7d. Heart angioplasty, balloon surgery of the heart, or a stent

pscvcdd

- 1 Yes
- 2 No

→ If "Yes", in past 3 months?

psangio

- 1 Yes
- 2 No

If "Yes", Rescreen

7e. Participated in cardiac rehabilitation

pscvcde

- 1 Yes
- 2 No

→ If "Yes", in past 3 months?

psrehab

- 1 Yes
- 2 No

If "Yes", Rescreen

**For staff use only:**

If yes on questions 7a, b, c, d or e, participant may be eligible at a later time.

Date of event or procedure: psd\_exc  (Month/Day/Year)

Call back: psd\_call1  (Month/Day/Year)

8. Do you have diabetes? (**not** diabetes during pregnancy)

psdiab

- 1 Yes
- 2 No
- 3 borderline

➔ **If Yes**, How old were you when you were diagnosed? psadiag  years old

**For staff use only:**

If participant says they are borderline, bring in to confirm.

**Pre-Screening Information - continued**

9. How do you treat your diabetes? Check all that apply.

psins value="1"  Insulin ➔ Has your diabetes ever been managed **without** insulin for a year? psinsyr

- 1 Yes
- 2 No

**For staff use only:**

If diagnosed prior to 25 years old and never managed without insulin for a year, exclude.

psothmd value="1"  Other diabetes prescription  
 ➔ How many months or years have you been on prescription medication for your diabetes? psomos  months psoyrs  years

psdiet value="1"  Diet **For staff use only:**  
 Verify type 2 diabetes during clinic eligibility screening.

psexer value="1"  Exercise **For staff use only:**  
 Verify type 2 diabetes during clinic eligibility screening.

psnone value="1"  None

10. What is your height?

pshgft  feet pshgtin  inches

11. What is your weight?

pswgt  lbs.

Body Mass Index: psbmi  kg/m<sup>2</sup>

**For Staff Use Only: (refer to chart)**

BMI >= 25 kg/m<sup>2</sup>

psbmi25

- 1 Yes
- 2 No excludes

BMI  $\geq$  27 kg/m<sup>2</sup> for insulin users

psbmi27

- 1 Yes
- 2 No excludes

Weight > 350

pswgt350

- 1 Yes
- 2 No

Yes excludes at clinic

discretion

12. What did you weigh three months ago?

psweigh3  lbs.

**For Staff Use Only:**

More than 10 pounds **weight loss**?

ps10more

- 1 Yes excludes
- 2 No

**Participant may be re-screened in 3 months.**

13. Do you drink alcoholic beverages?

(This includes 12 oz. beer, 4 oz. wine, or 1 shot (1.5 oz.) of liquor.)

psalc

- 1 Yes
- 2 No

→ If Yes,

About how many alcoholic beverages do you currently have in an average week? (This includes 12 oz. beer, 4 oz. wine, or 1 shot (1.5 oz.) of liquor.)

psdrks  beverages per week

More than 14? psalc14

- 1 Yes
- 2 No

### Pre-Screening Information - continued

14. Are you currently being treated for drug or alcohol abuse?

psdrugrx

- 1 Yes
- 2 No

15. Have you ever had any of the following?

Your heart stopped and doctors had to re-start it with an electric shock or defibrillator

psdefib

- 1 Yes
- 2 No

Kidney dialysis

pskdial

- 1 Yes
- 2 No

A pacemaker

pspmkr

- 1 Yes
- 2 No

Implanted defibrillator

psimdefib

- 1 Yes
- 2 No

Major organ transplant

psorgan

- 1 Yes
- 2 No

Schizophrenia, manic depression, or bipolar disorder

psschiz

- 1 Yes
- 2 No

Hepatitis B or C

pshep

- 1 Yes
- 2 No

Cirrhosis of the liver

pscirr

- 1 Yes
- 2 No

HIV

pshiv

- 1 Yes
- 2 No

16. Have you had a leg amputation associated with your diabetes?

pslegamp

- 1 Yes
- 2 No

17. Have you had extensive small bowel surgery or surgery for obesity?

pssurg

- 1 Yes
- 2 No

18. Do you have Cushing's syndrome?

pscush

- 1 Yes
- 2 No

19. Do you have acromegaly?

psacro

- 1 Yes
- 2 No

20. This question has been moved.

21. Have you had any of the following in the past 6 months?

Blood clot in your lung

psbclot

- 1 Yes
- 2 No

Hospitalization for depression

pshdep

- 1 Yes
- 2 No

**For Staff Use Only:**

If Yes to questions 20 and 21, participant may be eligible at a later time.

Date of excluding procedure: psd\_exc  (Month/Day/Year)

Call back: psd\_call1  (Month/Day/Year)

**Pre-Screening Information - continued**

22. Have you been treated for inflammatory bowel disease such as Crohn's disease or ulcerative colitis in the past year (Not irritable bowel syndrome)? psibd

- 1 Yes
- 2 No

23. Have you been diagnosed with or treated for any cancer except (Non-melanoma) skin cancer in the past 5 years? pscancer

- 1 Yes
- 2 No

➔ If Yes,

Probe for type



pscan\_sp

Probe for treatment

pscan\_rx

Some cancers will exclude, others may be allowed, i.e., stage 0-1 cervical cancers, cancers without chemotherapy, or cancers with good prognosis. Discuss with medical staff.

Does cancer or treatment exclude? psca\_exc

- 1 Yes
- 2 No

24. Can you walk 2 blocks (about 1/4 mile) without stopping?

pswalk

- 1 Yes
- 2 No
- 9 Don't know

25. Do you have active tuberculosis?

pstb

- 1 Yes
- 2 No

26. Are you currently taking steroid pills or shots such as prednisone or cortisone? (This does not include hormone replacement.)

psster

- 1 Yes
- 2 No

➔ If Yes, Which

ones? psstr\_sp

27. Are you currently taking medications for weight loss?

pswtmeds

- 1 Yes
- 2 No

➔ If Yes,

Are you willing to stop taking these medications? psstmeds

- 1 Yes
- 2 No

### Pre-Screening Information - continued

28 If female, are you currently pregnant or nursing?

pspreg

- 1 Yes
- 2 No
- 9 Male, not applicable

→ If Yes, May be re-screened in 6 months.

Participant now 6 months postpartum, not nursing, and eligible. psd\_pst6  (month/day/year)

29. Do any of the members of your household participate in or work for the Look AHEAD study?

psmem

- 1 Yes
- 2 No

Certain parts of the study require people to come for weekly visits.

30. Are you planning to move from the area within the next two years?

psmove2

- 1 Yes
- 2 No

→ If Yes, Explain: psmove\_sp

31. Are there times when you might be away for weeks or months at a time that might limit participation in the intervention?

psaway

- 1 Yes
- 2 No

→ If Yes, Explain: psaway\_sp

32. Are you currently participating in another research study?

psrstdy

- 1 Yes
- 2 No

→ If Yes, Explain: psrstdy\_sp

Approved by Eligibility Committee?

psstdyapp

- 1 Yes
- 2 No

### For Staff Use Only

3 How was participant screened?

3. psmeth

- 1 Phone, cold call
- 2 Phone, participant called or returned post card
- 3 In person

34 Eligibility status

psestat

- 1 Eligible

- 2 Ineligible
- 3 Patient refused
- 4 Pending

Explain: **pspend\_sp**

Call back: **psd\_call2**  (month/day/year)

35. Scheduled for eligibility screening visit?

**essched**

- 1 Yes
- 2 No

→ If Yes,

Date: **d\_es**  (month/day/year)

Time: **es\_hour**  : **es\_min**  **es\_am** value="1"  AM **es\_pm** value="1"  PM

36. Staff / Interviewer ID:

**staffid**

# PRE-SCREENING FORM (Interviewer Administered)

Patient ID	[affix ID label here]	Date Form Completed	<input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 20px; height: 20px;" type="text"/> <small>Month      Day      Year</small>
		Reviewed by	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
		Language	E

**Interviewer script:**

Hi, my name is \_\_\_\_\_ with the (*University of . . .*). Thank you for your interest in the Look AHEAD study. This is a study funded by the National Institutes of Health to determine if weight loss in people with Type 2 diabetes will reduce the risk of developing other health problems, such as heart disease and strokes. We would like to ask you a few questions about your health to see if you qualify for this study. All the information you give us will be kept confidential. Some of the questions are personal and may be sensitive. However, you may refuse to answer any question. Is this all right with you? Is this a good time for me to ask you these questions?

(yes) Great!

(no) When would be a more convenient time?

**Pre-Screening Information**

1. Has anyone interviewed you about the study before?

Yes →

When?  /  /   
Month      Day      Year

What was the outcome?

No

2. Where did you most recently hear about Look AHEAD? (Check only one.)

radio

**For staff use only:**  
 free radio     paid radio

website

television

**For staff use only:**  
 free TV     paid TV

poster / flyer

article in newspaper or magazine

physician or other health professional

advertisement in newspaper or magazine

**For staff use only:**  
 community     study staff

brochure

**For staff use only:**  
 How did you obtain the brochure?  
 mailed     display     work site

friend or relative

health fair or screening event

**For staff use only:**  
 Where was it?

other

**For staff use only:**  
 specify

don't remember

--

**Pre-Screening Information**

3. How old are you?

<input type="text"/>	<input type="text"/>	years old
----------------------	----------------------	-----------

4. Date of birth has been moved to  
Eligibility Screening Form A

<b>For staff use only:</b> 1 <input type="checkbox"/> less than 45 years old 2 <input type="checkbox"/> over 75 years old
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5. Male or female

1  male  
2  female

6. Are you Latino, Hispanic, or of Spanish origin?

1  Yes → 

Please continue with question 7
---------------------------------

  
2  No → 

Please continue with question 7
---------------------------------

7. Which of the following best describes you? (You may check more than one.)

1  African American / Black  
2  American Indian / Native American / Alaskan Native  
Specify 

--

  
3  Asian / Pacific Islander  
Specify 

--

  
4  White  
5  Other, specify 

--

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**Pre-Screening Information**

Have you "ever" had any of the following?

7a. Heart attack

1 <input type="checkbox"/> Yes →	In past 3 months?
2 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes → <input type="button" value="Rescreen"/>
	2 <input type="checkbox"/> No

7b. Stroke, ministroke or TIA

1 <input type="checkbox"/> Yes →	In past 3 months?
2 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes → <input type="button" value="Rescreen"/>
	2 <input type="checkbox"/> No

7c. Heart bypass surgery

1 <input type="checkbox"/> Yes →	In past 3 months?
2 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes → <input type="button" value="Rescreen"/>
	2 <input type="checkbox"/> No

7d. Heart angioplasty, balloon surgery of the heart, or a stent

1 <input type="checkbox"/> Yes →	In past 3 months?
2 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes → <input type="button" value="Rescreen"/>
	2 <input type="checkbox"/> No

7e. Participated in cardiac rehabilitation

1 <input type="checkbox"/> Yes →	In past 3 months?
2 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes → <input type="button" value="Rescreen"/>
	2 <input type="checkbox"/> No

**For event(s) in past 3 months 7a-7e**

<b>For staff use only:</b>																		
If yes on questions 7a, b, c, d or e participant may be eligible at a later time.																		
Date of event or procedure:																		
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Month	Day		Year															
Call back:																		
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		/			/													
Month	Day		Year															

**For Staff Use Only - For participants 45-54 years old**

If all answers for 7a-e are "no" and participant is less than 55, continue through question 11 only. Participant is ineligible.

If any answer (7a-7e) is "yes", continue completing form.

If any answer is "yes" for questions 7a-e in the past 3 months, participant is temporarily ineligible. Rescreen later.

8. Do you have diabetes? (not diabetes during pregnancy)

1 <input type="checkbox"/> Yes →	How old were you when you were diagnosed?					
2 <input type="checkbox"/> No		<table border="1"><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr></table> years old				
3 <input type="checkbox"/> Borderline						

<b>For staff use only:</b>
If participant says they are borderline, bring in to confirm.

--

**Pre-Screening Information**

9. How do you treat your diabetes?

Insulin →

Has your diabetes ever been managed **without** insulin for a year?

Yes

No →

**For staff use only:**

If diagnosed prior to 25 years old and never managed without insulin for a year, exclude.

Other diabetes prescription medication →

How many months or years have you been on prescription medication for your diabetes?

months  years

Diet →

**For staff use only:**

Verify type 2 diabetes during clinic eligibility screening.

Exercise →

**For staff use only:**

Verify type 2 diabetes during clinic eligibility screening.

None

10. What is your height?

feet  inches

**For staff use only: (refer to chart)**

BMI   
BMI 25 kg/m<sup>2</sup>

Weight > 350

No excludes

Yes excludes

at clinic discretion

BMI 27 for Insulin users

No excludes

11. What is your weight?  lbs.

12. What did you weigh three months ago?

lbs.

**For staff use only:**

More than 10 pounds **weight loss**?

Yes excludes

→ **Participant may be re-screened in 3 months.**

No

13. Do you drink alcoholic beverages? (This includes 12 oz. beer, 4 oz. wine, or 1 shot (1.5 oz.) of liquor.)

Yes →

About how many alcoholic drinks do you currently have in an average week? (This includes 12 oz. beer, 4 oz. wine, or 1 shot (1.5 oz.) of liquor.)

No  drinks per week

More than 14?  Yes

No



**Pre-Screening Information**

14. Are you currently being treated for drug or alcohol abuse?

Yes

No

**Clinic staff:**

AA is NOT a treatment for alcohol abuse.

15. Have you ever had any of the following?

Yes     No    your heart stopped and doctors had to re-start it with an electric shock or defibrillator

Yes     No    kidney dialysis

Yes     No    a pacemaker

Yes     No    implanted defibrillator

Yes     No    major organ transplant

Yes     No    schizophrenia, manic depression, or bipolar disorder

Yes     No    hepatitis B or C

Yes     No    cirrhosis of the liver

Yes     No    HIV

16. Have you had a leg amputation associated with your diabetes?

Yes

No

17. Have you had extensive small bowel surgery or surgery for obesity?

Yes

No

18. Do you have Cushing's syndrome?

Yes

No

19. Do you have acromegaly?

Yes

No

20. This question has been moved.

21. Have you had any of the following in the past 6 months?

Yes     No    blood clot in your lung

Yes     No    hospitalization for depression





**Pre-Screening Information**

22. Have you been treated for inflammatory bowel disease such as Crohn's or ulcerative colitis in the past year (not irritable bowel syndrome)?

Yes

No

23. Have you been diagnosed with or treated for any cancer except (non-melanoma) skin cancer in the past 5 years?

Yes →

Probe for type

No

Probe for treatment

Some cancers will exclude, others may be allowed, i.e. Stage 0-1 cervical cancers, cancers without chemotherapy, or cancers with good prognosis.

Discuss with Eligibility Committee. →

Does cancer or treatment exclude?

Yes

No

24. Can you walk 2 blocks (about ¼ mile) without stopping?

Yes

No

25. Do you have active tuberculosis?

Yes

No

26. Are you currently taking steroid pills or shots such as prednisone or cortisone? (This does not include hormone replacement.)

Yes →

Which ones?

No

27. Are you currently taking medications for weight loss?

Yes →

Are you willing to stop taking these medications?

No

Yes

No excludes

--

**Pre-Screening Information**

28. If female, are you currently pregnant or nursing?

- 1  Yes → May be re-screened in 6 months.
- 2  No
- 9  Male, not applicable

Participant now 6 months postpartum, not nursing, and eligible.

		/			/		
Month	Day		Year				

29. Do any members of your household participate in or work for the Look AHEAD study?

- 1  Yes
- 2  No

Certain parts of the study require people to come for weekly visits.

30. Are you planning to move from the area within the next two years?

- 1  Yes → Explain:
- 2  No

31. Are there times when you might be away for weeks or months at a time that might limit participation in the intervention?

- 1  Yes → Explain:
- 2  No

32. Are you currently participating in another research study?

- 1  Yes → Explain:   
Yes requires approval by Eligibility Committee \_\_\_\_\_
  - 2  No
- |                                    |
|------------------------------------|
| Approved by Eligibility Committee? |
| <input type="checkbox"/> Yes       |
| <input type="checkbox"/> No        |

**If Eligible:**

Based on these questions, you may be eligible to participate in the Look AHEAD Study. We would like to invite you to visit the clinic to ask you a few more questions about your medical history, measure your blood pressure, and take a blood sample. When are you available to come to our clinic? We have both day and evening appointments available. Great!

**If Ineligible:**

Based on these questions, it looks like you are not eligible for the Look AHEAD Study. We really appreciate your interest in the study and hope that we can contact you in the future for other studies related to diabetes or weight loss.

--

**For staff use only:**

33. How was participant screened?

- 1  phone, cold call
- 2  phone, participant called or returned post card
- 3  in person

34. Eligibility status

- 1  Eligible
- 2  Ineligible
- 3  Patient refused

4  Pending: Explain ; Call back / /   
Month Day Year

35. Scheduled for screening visit?

1  Yes → / /  Time :   AM  
2  No  PM  
Month Day Year

36. Staff/Interviewer ID

First Name

MI

Last Name

Acrostic