

COVER PAGE

Addressing Basic Needs to Improve Diabetes Outcomes in Medicaid Beneficiaries

NCT03940209

March 8, 2024

Last annual continuing review from Washington University IRB triggering the update of the consent form expiration date; no other changes were made to the consent document or procedures, so no other updates recorded.

December 1, 2020

Interested individuals were asked to provide verbal informed consent before completing study eligibility questions, then only among those eligible and interested, individuals were informed about their rights and responsibilities as research participants. Both documents are included here.

September 15, 2018

Data analysis plans submitted as part of the grant application are included following informed consent documents.

Hi. May I speak with **[insert participant name]**?

My name is **[insert interviewer name]** from Washington University in St. Louis. We are partnering with your health plan, Louisiana Healthcare Connections.

I am calling you to invite you to be part of a new research project with Louisiana Healthcare Connections to test new ways to improve members' lives and health. All members who participate will complete a few phone interviews and will receive gift cards each time they do. We can do the first survey today and you will get a \$50 gift card. Are you interested in hearing more about this project?

[If no, end the call. If yes,] Ok, great. I will need to read you some consent information before we start. If you agree to be in the study, we will also mail you a copy of this information.

First, can you confirm your first and last name and date of birth? **[confirm with record]**
Can you confirm your street address for me? **[confirm with record]**

If they have moved: Your street address has changed from what I have on file. Do you remember your last street address? [If not: I'm sorry, I can't continue this call without verification. Thanks for your time.]

We are doing the research study to learn more about the life experiences of people with type 2 diabetes. Some people in the study will participate in a program where they will get help with unmet basic needs. Basic needs are not met when people have trouble paying for things like food, utilities or medicine. Some people in the study will get help finding ways to meet unmet basic needs.

The National Institutes of Health is paying for this research study. About 500 people will be in this study. This study is being done by Washington University and Louisiana Healthcare Connections.

If you agree to be in the study, you will be in it for about one year. You will complete 4 surveys over the phone. Surveys will take 30 minutes or less to do. If you have time, you can take the first survey with me today. If not, we can set up a better time to call you back. After the first survey, someone from the research team will call you to do a survey three more times: about 3, 6, and 12 months from today. If you agree to be in the study, your health plan will give Washington University certain information about your health from your health records. This includes your HbA1c blood glucose test results, age, and medical information from a year before the study until a year after the study.

You might have someone help you with any unmet basic needs. If you are in this part of the study, someone from Louisiana Healthcare Connections will call you in the next few days to talk to you about how she can help you. A computer program will choose who does this part of the study.

Louisiana Healthcare Connections may audio record some phone calls for quality and training purposes. We will use an ID number instead of your name to protect your identity. All audio recordings will be saved with passwords. Only the study team will have your data. The audio files will be erased after we write down the information we need.

There are some risks from doing this study. You might not like some of the survey questions because they might feel private. Some questions ask about income, health status, and problems meeting basic

needs. If you feel uncomfortable, you can skip questions at any time. You can also stop being in the study at any time.

One risk of being in this study is that study information about you may be shared by mistake. We will do our best to keep the information about you secure. You may or may not benefit from being in this study. But maybe other people might benefit in the future from what we learn.

You will not have to pay any money for being in this research study. You will be paid for being in this study. You will get a \$50 gift card for the first survey you complete and \$25 for each follow up survey you complete. If you complete all the study parts, you will get a total of \$125 in gift cards. You will be asked for your social security number and mailing address for us to pay you. Your social security number is used for payment only. It will not be used for anything else. You don't have to provide your social security number if you don't want to.

We will keep the data you give us confidential. We will keep your name separate from your answers. You will not be identified if we write a report about this study. We will keep your data on a computer. The computer is protected. Files with your data will be in a locked cabinet. Some groups that may look at and copy records are:

- Federal Regulatory Agencies
- Washington University and their Institutional Review Board (a group that reviews and approves research studies)
- Washington University Human Research Protection Office

It is up to you if you want to be in this study. You may choose not to be in the study at all. If you decide to be in this study, you may stop at any time. If you decide to stop, any data that we have about you will stay in the records. It can't be removed. If you decide not to be in this study or stop being in the study at any time, there is no penalty. You will not lose any benefits you qualify for.

To protect your information, this research has a Certificate of Confidentiality from the federal government. The researchers will not give information that would tell other people who you are in a legal or court meeting or to anyone who is not part of the research except if:

- there is a law that makes the researchers tell the information, such as to report child abuse, or if they knew you would hurt yourself or someone else;
- you say yes to giving your information, like in this consent form; or
- it is used for other scientific research allowed by federal law.

You can share your information about this study with anyone at any time. You may also let the research team give the information to other people outside the research.

We want you to ask questions. Call or email Monday through Friday 9 a.m. to 5 p.m.

- If you have any questions about the research study, contact Lauren Grimes toll free at 1-855-868-7887 or at 314-935-2721. Or email her at l.grimes@wustl.edu.
- If you feel hurt because of the study or have worries or complaints, please contact Matthew Kreuter at 314-935-3701 or mkreuter@wustl.edu.
- Information about being a study participant is on the web site: hrpo.wustl.edu/participants. Call 1-800-438-0445 to give your thoughts about being in a study or to speak to someone besides the

study staff.

This verbal consent form is not a contract. It describes what will happen during the study if you participate. You are not waiving any legal rights by being in this study.

Do you have any questions? **[Answer any questions]**

Would you like to participate? **[Document verbal consent in the research record.]**

[If consent to participate: confirm eligibility]

To make sure that you qualify for this study, I first need to ask you a few questions.

How old are you today? [If <18 or >75: Sorry, you are not eligible to participate. Thank you for your time.]

Do you have type 2 diabetes? [If no: Sorry, you are not eligible to participate. Thank you for your time.]

A test for hemoglobin A1c measures the average level of blood sugar over the past 3 months. It is usually done by a blood sample sent to a lab. A1c normally ranges between 5.0 and 13.9. What was your MOST RECENT A1c level (lab value)? _____ [If <7.0: Sorry, you are not eligible to participate. Thank you for your time.]

[For those who do not know their most recent A1c level:] If you do not know your most recent A1c level, do you know if it is:

- Less than 5.9%
- 6.0% to 6.9%
- 7.0% to 7.9%
- 8.0% to 8.9%
- More than 9.0%
- Unsure

[If <7.0 or Unsure: Sorry, you are not eligible to participate. Thank you for your time.]

Do you consider yourself to be male, female or other? _____

If female:

Are you currently pregnant? [If yes: Sorry, you are not eligible to participate. Thank you for your time.]

Have you ONLY ever been diagnosed with gestational diabetes and NOT type 2 diabetes? [If yes: Sorry, you are not eligible to participate. Thank you for your time.]

The next few questions ask about your current living situation.

If asked “why are you asking”, respond with “It is very important to understand what is going on in each person’s life because, many times, it can affect their health. Our study is about how your life situation can affect health”

1. How would you rate the safety of your neighborhood? (very unsafe, unsafe, safe, very safe)
2. Thinking about the number of people living in your home, would you say you have:
(not enough space, about the right amount of space, more than enough space)
3. How likely is it that you will have reliable transportation in the next month to get to appointments, work, or the things you need for daily living? (very unlikely, unlikely, likely, very likely)
4. How likely is it that you and others in your home will get enough to eat in the next month?
(very unlikely, unlikely, likely, very likely)
5. How likely is it that you will have a place to stay all of next month?
(very unlikely, unlikely, likely, very likely)
6. How likely is it that you will be able to pay for your current electric, gas, or water bill in full in the next month? (very unlikely, unlikely, likely, very likely)
7. How likely is it that you will have enough money in the next month for necessities like food, housing, and clothing? (very unlikely, unlikely, likely, very likely)
8. How likely is it that you will have enough money in the next month to deal with unexpected expenses? (very unlikely, unlikely, likely, very likely)
9. How likely is it in the next month that you will have people to spend time with and enjoy their company? (very unlikely, unlikely, likely, very likely)
10. How likely is it that someone will threaten to hurt you physically in the next month?
(very unlikely, unlikely, likely, very likely)
11. How likely is it that you will have trouble finding or paying for childcare in the next month?
(very unlikely, unlikely, likely, very likely)

[If participant does not have at least 1 unmet basic need (likely/very likely): Sorry, you are not eligible to participate. Thank you for your time]

Does this individual have a cognitive or hearing impairment that may make filling out a phone survey difficult or impossible? Yes No [Caller will use judgment for this. If caller feels that the subject has a cognitive or hearing impairment: Sorry, you are not eligible to participate. Thank you for your time]

Great, you are eligible to participate.

We will need to contact you by phone to complete the follow up surveys. What phone numbers would you be willing for us to call you?

Home:

Cell:

Work:

Other1: [type]_____

Other2: [type]_____

Other3: [type]_____

Do you have a preferred day and time of day that we should call you? _____

Are you willing to receive **text messages** from us related to your participation in the study?

For example, if we can't reach you by phone, we may text you a note that we tried to reach you and ask if you want to set up a time to do the next survey. We do not plan to send regular texts. We will not sell your phone number. We will not share your phone number with anyone outside of this study. We will not include any personal health information in the text message.

No

If Yes – which numbers would you like us to send texts to?

- ☐ Home
- ☐ Cell
- ☐ Work
- ☐ Other1
- ☐ Other2
- ☐ Other3

Are you willing to receive **email messages** from us related to your participation in the study?

For example, if we can't reach you by phone, we may email you a note that we tried to reach you and ask if you want to set up a time to do the next phone survey. We do not plan to send regular emails or enroll you in an email program. We will not sell your email address. We will not share your email address with anyone outside of the study. We will not include any personal health information in the text message.

No

If yes – which email address(es) would you like us to use?

Email 1 _____

Email 2 _____

You are now enrolled in the study. We can do your first survey right now. It will take about 30 minutes. We will send you your first \$25 gift card once you finish the survey. Would you like to get started or would you like someone to call you back to do it another time?

[If now – transition to survey]

[If later-]

What would be a good day and time for someone to call you to do the survey in the next few days?

FOR IRB USE ONLY
IRB ID #: 201811020
APPROVAL DATE: 03/08/24
RELEASED DATE: 03/08/24
EXPIRATION DATE: 03/07/25

[document preference in study record]

Thank you for your time today.



RESEARCH STUDY INFORMATION SHEET

Thank you for agreeing to be in the *For You Bayou* study. We are giving you this information in writing for you to keep.

PURPOSE OF THE STUDY

We are doing the study to learn more about the life experiences of people with type 2 diabetes. Some people in the study will participate in a program where they will get help with unmet basic needs. Basic needs are not met when people have trouble paying for things like food, utilities or medicine. Some people in the study will get help finding ways to meet unmet basic needs.

ABOUT THE STUDY

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You have agreed to be in the study. You will be in it for about one year. You will complete 4 surveys over the phone. Surveys will take 30 minutes or less to do. Someone from the research team will call you to do a survey about 3, 6, and 12 months after your first survey. Your health plan will give Washington University certain information about your health from your health records. This includes your HbA1c blood glucose test results, age, and medical information from a year before the study until a year after the study.

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RISKS AND BENEFITS OF BEING IN THE STUDY

By being in the study, you may receive some benefits. But there may be some risks. You might not like some of the survey questions because they might feel private. Some questions ask about income, health status, and problems meeting basic needs. If you feel uncomfortable, you can skip questions at any time. You can also stop being in the study at any time.

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You will not have to pay any money for being in this research study. You will be paid for being in this study. You will get a \$50 gift card for the first survey you complete and \$25 for each follow up survey. If you complete all the study parts, you will get a total of \$125 in gift cards. You will be asked for your social security number and mailing address for us to pay you. Your social security number is used for payment only. It will not be used for anything else. You don't have to provide your social security number if you don't want to.

YOUR PERSONAL INFORMATION IS PROTECTED

Louisiana Healthcare Connections and Washington University in St. Louis will do everything we can to protect your personal information. We will keep the data you give us confidential. We will keep your name separate from your answers. You will not be identified if we write a report about this study. We will keep your data on a computer. The computer is protected. Files with your data will be in a locked cabinet. Some groups that may look at and copy records are:

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HOW TO CONTACT US

We want you to ask questions. Call or email Monday through Friday 9 a.m. to 5 p.m.

FOR IRB USE ONLY IRB ID #: 201811020 APPROVAL DATE: 03/08/24 RELEASED DATE: 03/08/24 EXPIRATION DATE: 03/07/25
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RESEARCH STRATEGY - DATA ANALYSIS PLAN

D5.1 Sample size and power calculations.

Aim 1. With approximately 40,000 members with HRS data in 2016, we will have more than adequate sample sizes for our descriptive aims. For simple correlations, only 127 people are needed to detect small effects $r=.10$ as statistically significant with power=80% and $\alpha=.05$. The proportion of members who report unmet basic needs, chronic conditions, ED visits, and hospitalizations, and the variability across socio-demographic variables are unknown and will impact the inferential statistics that can be performed. We will specifically administer HRS to members with type 2 diabetes in Year 1 to increase the availability of new HRS basic needs data for Aim 1 analyses and support Aim 2 recruitment.

Aim 2. The 8847 adult members with type 2 diabetes not already in case management would be eligible for recruitment (Table 1). With a sample of 265 participants with type 2 diabetes, we would have 90% power to detect a 0.4%^{163,164} mean difference ($SD=2$) in HbA1c between the intervention and usual care using a two-tailed paired t-test with $\alpha=.05$. This is a conservative estimate based on previous studies.¹⁶³⁻¹⁶⁶ Change in HbA1c = 0.5% is considered clinically meaningful^{21,22} and every 1% reduction is associated with significant risk reduction.^{19,20} To compensate for an estimated 30% loss by 12 month follow up due to participant's refusal or loss of Medicaid coverage, and the unknown pattern of HbA1c testing in our sample, we propose to enroll 500 (5.7%) participants at baseline ($n=250$ in each group) over the 2.5 year recruitment period (See Timeline Table 2). With $N=500$ and a two-tailed chi-square test, we also will have >80% power to detect a 10% difference in the reduction of HbA1c by 0.5% when the proportions of each study group are $\leq 25\%$.

D5.2 Aim 1 analyses will use HRS data from all adult Medicaid members and additional administrative data. Primary Analyses (Year 1): (1) We will use descriptive statistics to characterize the unmet basic needs of the Medicaid population as well as their age, race, gender, BMI, chronic conditions, and tobacco use and basic utilization variables collected by the HRS (see D3.3). We will test for any differences in the two samples obtained for Aim 1 analyses (see D3.2) to inform our plan to pool data for inferential analyses. (2) Bivariate and multivariable analyses will be conducted to examine the associations between the number and type of unmet basic needs and the other HRS variables. For example, tobacco use may be associated with greater financial and food insecurity¹⁶⁷⁻¹⁷⁰ and BMI may be positively associated with food insecurity.^{171,172} We also will conduct stratified or subgroup analyses of Medicaid members to compare the pattern and associations of unmet needs for diabetes with other types of chronic conditions reported in the HRS. Total unmet needs may be greater among members with mental health conditions,¹⁷³ but job security may be reported by more members with diabetes and cardiovascular disease.¹⁷⁴ Differences by group will be compared using chi-square tests or logistic regression for categorical outcome variables and by t-tests, linear regression or appropriate non-parametric tests for continuous outcome variables. (3) Consistent with our prior work,¹² we will also explore possible latent classes of unmet basic needs and what socio-demographic and health-related variables distinguish between classes.

D5.3 Secondary analyses will link Year 1 HRS data with additional utilization variables and provider information from administrative data (see D3.3) collected ≤ 12 months post-HRS completion to examine prospective impact of unmet needs. For members with HRS data analyzed in Year 1 who remain health plan members in Years 2-5, we can assess longer-term influences and changes in unmet needs and other variables. Because HRS data are continuously collected, we can conduct analyses to describe any variability in the reported unmet needs and their correlates over time, which will inform the conclusions drawn from Aims 2-3 results. Other secondary data analyses will emerge from the unique opportunity to link HRS data with administrative data from a health plan for a large Medicaid population by an interdisciplinary research team with transdisciplinary goals.

D5.4 Aim 2 analyses will involve trial participants' data from surveys, HRS, and administrative sources. Preliminary Analyses. We will use descriptive statistics to report the number and type of unmet basic needs, socio-demographics, chronic conditions per HRS, and utilization per administrative data. Baseline differences

between study groups will be examined so that covariates can be included in final analyses as needed. Baseline associations will be examined using chi-square tests or logistic regression for categorical variables and by t-tests, linear regression or appropriate non-parametric tests for continuous variables.

D5.5 Primary Analyses. Consistent with previous intervention trials designed to reduce HbA1c,¹⁶³⁻¹⁶⁶ we will conduct paired t-tests to test our primary hypothesis that participants who receive the basic needs navigation intervention will have a greater reduction in HbA1c (M=0.5%) compared with participants receiving usual care. “Baseline HbA1c” will be defined for all trial participants as the test result between the date of enrollment and 90 days prior, per eligibility criteria. Enrollment date is defined as the date the baseline survey is completed. Although unexpected, if a participant has more than one HbA1c result in that 3 month interval, we will use the result closest to the enrollment date. Follow up HbA1c will be defined as the first test result between the date marking 6 months post-baseline (also intervention end date & survey due date) and the date marking 12 months post-Baseline HbA1c. We expect nearly all participants will have at least one HbA1c test every 12 months. Participants who have more than one test result in the follow up period will contribute to multiple analyses examining intervention effects at different time intervals. For the primary analysis, if a participant has more than one result, we will use the result closest in time to the 6 month post-baseline date. We will conduct intent-to-treat analyses and impute the final value from the last HbA1c value on record (last observation carried forward approach) for all participants lost to follow up or who have missing data. Consistent with prior analyses using our basic needs measures,^{12,70,71,119} we will examine associations between diabetes-related variables and number and type of unmet basic needs to elucidate the way basic needs impact HbA1c and secondary outcomes. We also hypothesize that a greater proportion of participants who received the intervention will reduce their HbA1c by a clinically meaningful amount (0.5%) compared to usual care participants. Proportions will be compared using chi-square for bivariate analysis and logistic regression for multivariable analyses involving covariates of HbA1c and study group differences measured at baseline.

D5.6 Secondary Analyses. The rich measures collected at multiple time points from our large and diverse Medicaid sample will provide many opportunities for secondary data analyses and sensitivity analyses comparing results across different measures (e.g., self-report vs. objective measures) and operationalizations (e.g., mean change vs. meaningful change in HbA1c; number vs. type of unmet basic needs). We will compare results of analyses involving HbA1c measured via self-report vs. medical record and examine the concordance between the two measures. We will examine the intervention effect among participants by socio-demographics, total number and latent classes of basic needs, and by level of engagement among participants assigned to the intervention group (# of navigator calls; weeks in navigation, # of problems addressed). If significant, such intervention moderator variables would identify subgroups of participants for whom the intervention was more or less effective. Similarly, comparing the relative effects of the intervention on secondary outcomes will identify whether the intervention is more effective for certain outcomes. Previous research has shown that food insecurity is related to glucose control, but it may be that physical safety needs and financial strain are more strongly related to perceived stress and diabetes burden than HbA1c, which might warrant tests of mediation (See D5.7). For participants with multiple HbA1c results in the ≤12 months pre-intervention, we can create new variables reflecting trends. For example, we expect that participants with linearly decreasing HbA1c values before the intervention will have greater odds of having clinically meaningful reductions in HbA1c during the study follow up than participants with missing data or stable HbA1c values over time. We also will examine the effect of baseline variables on study attrition and intervention engagement. Multinomial regression will be used with baseline data for all intervention and control participants to identify differences by groups defined as having all, some, or no follow up data. Alternatively depending on the pattern of missing data, groups could be defined by time in the study: completers, early drop outs, and late drop outs.