Philly Family Trust Study: A Pilot Randomized Controlled Trial of an Unconditional Cash Transfer to Improve Health Behaviors Among Adults with Chronic Diseases

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1. Abstract

Health behaviors are major, modifiable risk factors for the development and progression of chronic diseases, which account for a large proportion of all deaths in the US and contribute to disparities in premature mortality based on both income and race. There is substantial evidence, for example, that behaviors like smoking, physical inactivity, and unhealthy diet are associated with an increased risk of cardiovascular disease (CVD), as are modifiable factors such as blood pressure, cholesterol, body mass index, and fasting glucose. A growing body of research suggests that poverty may affect health behaviors through financial and psychological pathways. However, few studies have rigorously examined the effects of poverty alleviation interventions on health behaviors, particularly among individuals at high risk for CVD. Even fewer studies have examined potential psychological mechanisms by which anti-poverty interventions might influence health behavior. This pilot project will examine the effect of unconditional cash transfers, an economic intervention that is gaining traction among policymakers, on risk factors for CVD and other chronic diseases. The project will focus on low-income adults in Philadelphia who have at least one health risk factor for CVD (type 2 diabetes/pre-diabetes and/or hypertension) and examine whether short-term, unconditional cash transfer payments result in changes in objective and self-reported health outcomes. Our second aim will examine potential psychological mechanisms through which the cash transfer intervention may affect study participants' behavior, including mental health, psychosocial stress, bandwidth, and future orientation. Our third aim will use qualitative methods to understand participants' experiences with this study. The project activities will include developing and testing the cash transfer intervention (Stage 1) as well as basic science analysis of mechanisms of change (Stage 0).

2. Objectives and Aims

We will conduct a pilot trial of a short-term unconditional cash transfer provision and evaluate its effects on health behaviors and outcomes. Our overall goals are to assess the feasibility and acceptability of the intervention, to measure key outcomes that may be affected by the intervention, and to identify plausible intervention effect sizes that can be used to conduct a larger trial. Our specific aims are:

Aim 1: Determine the effect of an unconditional cash transfer provision on specific health behaviors that influence CVD risk, financial outcomes, and health risk factors that are directly related to insufficient financial resources (food and utility security) (Stage 1, create and test new behavioral interventions). In partnership with Penn Family Care clinics, we will identify potential participants who may be eligible for the study. We will then enroll and randomize about 100 low-income adults with either hypertension or pre-diabetes/diabetes to either: 1) usual care or 2) eight cash transfer payments of $125 every two weeks (for a total of $1000 over 4 months). At baseline and at 3 months (before the eighth payment, to minimize the influence the intervention ending has on follow up measures), we will assess our **primary outcomes** of health behaviors (health care utilization, medication adherence, smoking behavior, and alcohol use), financial outcomes (health care expenditures, financial stress) and health risk factors associated with insufficient financial resources (food and utility insecurity). We will also examine secondary health outcomes including self-reported health-related quality of life, and objectively measured body mass index and blood pressure.

Aim 2: Assess potential psychological mechanisms through which the intervention influences cardiovascular health (Stage 0, research on mechanisms of change). At baseline and 3 months, we will measure several factors that are hypothesized to affect participants' health behaviors and cardiovascular health, including their mental health, psychosocial stress, mental bandwidth, and time preferences.

Aim 3: Conduct in-depth qualitative interviews with research participants to better understand intervention effects and mechanisms and experiences with the study. Our primary outcomes will be a series of themes related to participants' experience as a part of a guaranteed basic income study and perceptions of how the study did or did not help support their physical and mental health.

3. Background

Health behaviors are major, modifiable risk factors for the development and progression of chronic diseases, which account for a large proportion of all deaths in the US and contribute to disparities in premature mortality based on both income and race.[1] There is substantial evidence, for example, that behaviors like smoking, physical activity, and diet are associated with an increased risk of cardiovascular disease (CVD), as are modifiable factors such as blood pressure, cholesterol, body mass index, and fasting glucose.[2,3] Although some interventions to target these risk factors for CVD have had considerable success –e.g., tobacco policies like taxes and clean indoor air laws –many adults remain at high risk for CVD and large racial and economic disparities in chronic disease risk continue to persist. This is in part because few policies have addressed poverty as a fundamental driver of health.

A growing body of research suggests that poverty affects human behavior through financial and psychological mechanisms. In addition to the readily apparent economic pathways by which poverty may reduce one's engagement in health-promoting behaviors (e.g., inability to access or afford healthy food or preventive health services), recent studies indicate that poverty also has negative psychological consequences.[4] In particular, poverty and chronic indebtedness can increase stress and consume mental bandwidth. Intriguingly for the study of health behavior, recent research suggests that poverty may result in less future-oriented decision-making.[5] Despite growing interest in the psychological consequences of poverty, however, few studies have rigorously examined the effects of poverty on health behaviors and the mechanisms by which poverty alleviation might influence behavior. Determining the impact of poverty alleviation interventions on health behaviors and CVD risk – and the channels through which these effects operate – will fill important scientific and policy gaps.

Guaranteed income programs that provide recurring monthly payments of $500 or more are being piloted in several cities in the US, and the use of direct cash transfers has also been adopted at the national level (e.g., direct payments in American Rescue Plan). While emerging evidence suggests that cash transfers improve socio-economic outcomes, there are significant evidence gaps as to whether they also improve health behaviors, reduce chronic disease risk factors, and lessen socio-economic disparities in chronic disease risk. The project activities will include developing and testing the cash transfer intervention (Stage 1) as well as basic science analysis of mechanisms of change (Stage 0). Findings from the project will provide suggestive evidence of whether bold economic interventions that address the economic and psychological consequences of poverty have the potential to promote health behavior. If

successful, the findings will inform a larger-scale efficacy trial that will examine whether guaranteed income interventions reduce CVD risk among low-income adults.

4. Study Design

We will conduct a two-arm randomized controlled trial to examine the feasibility, acceptability, and likely effect of an unconditional cash transfer intervention on self-reported and objectively measured health behaviors and outcomes among low-income adults. A detailed outline of study design can be found in Study Procedures.

4.1. Study Duration

Randomized-controlled trial duration: The duration of study participation will be 4 months after enrollment. We expect the total duration of the study to last 8 months given the expected time to recruit and enroll all participants. We will aim to recruit participants from March 2023 through July 2023. We estimate that the study will be completed by October 2023.

Qualitative interview duration: Participants' engagement in this part of the study is expected to last approximately 60 minutes.

4.2. Target Population

The study population will be comprised of primary care patients at Penn Family Care in West Philadelphia. We will enroll a total of 100 participants — 50 will be assigned to the usual care arm (Arm 1) and 50 will be in the intervention arm (Arm 2).

Participants enrolled by Penn Researchers: 100

Participants enrolled by Collaborating Researchers: 0

4.3. Inclusion Criteria:

- Age 18 years or greater
- Pennsylvania Medicaid enrollee
- At least one clinic visit at Penn Family Care within six months of the start of the study
- Diagnosis of pre-diabetes/diabetes and/or hypertension
- Actively prescribed a medication for diabetes or hypertenstion
- Regular resident of the Philadelphia metro area without plans to leave in the next 6 months

4.4. Exclusion Criteria:

- Does not meet all of the inclusion criteria
- Unable to provide consent
- Non-English speaker
- Cognitive impairment, per PIs discretion
- Cannot be in the same household as another enrolled study participant

4.5. Populations vulnerable to undue influence or coercion

All participants in this study will receive the usual standard clinical care. Participants will be informed that this study is voluntary, and they are free to withdrawn at any time.

5. Study Procedures

5.1. Procedures

Clearance was obtained from Family Medicine Research Committee indicating that we will not need to inform physicians at Penn Family Care that their patients will be contacted for recrutiment. A list of potentially eligible participants will then be generated by Aaron Richterman (PI, UPHS Physician who has completed SlicerDicer research training through Penn KnowledgeLink) through the electronic medical record based on the inclusion criteria using EPIC's SlicerDicer tool. These potentially eligible participants will be routed from SlicerDicer to an EPIC Report for access to identifiable information after entering the IRB-approved protocol number.

- The list of variables that will be pulled include:
    - MRN
    - Patient name
    - DOB
    - Age
    - Sex
    - PCP
    - Pt Portal Status
    - Last Visit Date
    - Last Visit Provider
    - Last PCP visit
    - Next PCP visit
    - Payor
    - Patient Type
    - Active FYIs
    - PCP Department
    - Zip Code
    - Rsch.Cntct.Pref
    - Phone

Study staff will not have any involvement in the clinical care of potential participants. Recruitment will be done using a batched approach starting with 1) MyPennMedicine messages, followed by 2) Text messages, and finally 3) QR Codes in the clinic. Potentially eligible patients will first be contacted using a MyPennMedicine message with a REDCap survey link to our study interest form. For participants who respond to the survey interest form, the variables phone, patient name, DOB, and last visit date will be added to our REDCap project. Participants that do not complete an interest form via MyPennMedicine will be sent a text asking if they'd like to complete the online interest form via text, or if they would like to receive a call by research study staff with additional information about the study. Research staff will follow-up with a phone call for those who not complete the interest form via text and ask if they'd like to complete the interest form over the phone. Research staff will be able to confirm the participant's identity over the phone by using name and DOB. Survey interest forms will be matched with the eligible EHR list pulled from SlicerDicer to confirm eligibility. Eligible participants will be contacted by phone to confirm interest in the study and schedule the baseline appointment. Study staff will describe the intervention and inform potential participants that the cash transfers may lead to SSI slightly overpaying them and asking for money back, which they can ask SSA to waive. Participants will also be informed that our team has received a notice from the state of Pennsylvania that the study payments will not count as income for state programs such as SNAP, TANF, and Medicaid, so their eligibility for these programs **will not** be affected by their participation. Eligible and interested potential participants will then be scheduled for an in-person baseline visit with study staff, where informed

consent will be obtained (see consent procedures, below, for additional details). The in-person visits will take place at 3535 Market Street at the Psychology of Eating and Consumer Health Lab at the University of Pennsylvania (PI: Roberto).

Written consent will be obtained from participants during the initial in-person visit, prior to the study session. A single consent will be used for all study activities except the qualitative interviews, which will involve a separate consent process. The following data will be collected during the baseline assessment:

- Survey data – Study staff will administer an in-person REDCap survey that will capture the following:
    - Sociodemographics including age, sex, gender, address of residence, zipcode,race, ethnicity, sexual orientation, marital status, schooling attainment
    - Economic data including work, income sources (including government programs such as SNAP, TANF, and WIC), and total household income
    - Food security assessment in accordance with USDA methodology[6]
    - Utility security (Home Energy Insecurity Scale)[7]
    - Housing data including living situation, household composition, and housing security
    - Health-Related Quality of Life (CDC HRQOL-4)[8]
    - Health Spending
    - Tobacco use (CDS-5)[9]
    - Alcohol use (AUDIT-C)[10]
    - Medication Adherence (ARMS)[11]
    - Kessler Psychological Distress Scale (K6+)[12]
    - CFPB Financial Stress Scale[13]
    - Perceived Stress Scale (short form)[14]
    - State Trait Anxiety Inventory (State questions only)[15]
    - Time preference measures[16]
    - Acceptability of Intervention Measure (follow up only)[17]
- Electronic Medical Record
    - Number of ED/Hospital visits in last 3 months
    - Number of non-ED visits in last 3 months
    - Number of chronic medications
    - Chronic medical conditions (problem list)
- Objective data (measured by study staff and entered directly into REDCap)
    - Height
    - Weight
    - Blood pressure
- Cognitive testing (mental bandwidth)
    - Psychomotor Vigilance Task (PVT)[18]
        - PVT is a computer-based task that assesses attentional vigilance, asking participants to press a button when a stimulus appears on a screen and measuring reaction time and accuracy
        - For this computer-based task, no identifying information is entered, and immediately upon completion the program puts out the relevant data (e.g. reaction time, accuracy), which will be directly and immediately entered into REDCap by study staff
- W9 and C2
    - W9 (including SSN) and C2 will be collected for all participants . These will be completed by paper and stored in a secure location only accessible by study

personnel. At the end of the study, W9 forms will be scanned and sent via SecureShare to Sarah Boyer to be logged into the Greenphire W-9 Database. Once scanned, paper copies will be shredded.

At the end of the baseline assessment, participants will be randomized using a permuted block technique with block size of 4 to either usual care (Arm 1) or to the unconditional cash transfer intervention (Arm 2). Participants in Arm 2 will receive an unconditional cash transfer of $125 every 2 weeks for 8 payments via ClinCard, for a total of $1000. In addition, 16 participants will also be randomly selected to receive a blood pressure cuff to take home. Of these 16, 8 will be blood pressure cuffs that wirelessly transmit readings to an app on their mobile phone.Participants that receive a blood pressure cuff will be askedto take a blood pressure reading weekly for the duration of their enrollment period, and record their reading via a REDCap survey link sent by text. Those receiving a wireless blood pressure cuff will transmit their readings wirelessly, as well as record their reading in the weekly REDCap survey link. The goal of this procedure is to pilot test the feasibility of this technology and approach for a future, larger study.

All participants will be asked to return for an in-person assessment at month 3. This assessment will include all elements of the baseline assessment. Additionally, intervention participants will complete the Acceptability of Intervention Measure[17] and be asked a survey question about how the cash transfer was used. Participants randomized to receive a blood pressure cuff will also be asked to complete a short survey regarding their acceptability and use of a blood pressure cuff at home.

Via ClinCard, all participants will receive $25 compensation for completing the baseline assessment, and $50 for completing the follow-up assessment. Participants providing at-home blood pressure readings will receive an additional $3 per reading (maximum $3 per week, $48 total).

Qualitative interview procedures: During the 3-month study visit, up to 35 interested study participants (25 intervention, 10 control) will be selected to participate in a follow up qualitative interview to better understand their experience in the study, including the mechanisms by which poverty and cash transfers may affect health behaviors (see attached in-depth interview guides). Participant interest will be obtained during the baseline visit and documented in a secure REDCap database. Once participant interest is confirmed, research staff will randomly select 35 interested participants and schedule their interview at the end of their 3-month study visit through Outlook using only their Record ID. A copy of the verbal informed consent form will be provided at the time of this visit, so they have time to review prior to the interview. Once interview appointments are scheduled, participants will receive a reminder text the week prior and the day before their interview to remind them about the time/date of their interview.

The qualitative research interviewer will call the research participants at the phone number that they provide our research team in REDCap. Prior to conducting the qualitative interviews, the research interviewer will run participants through a verbal consent process (a copy of the verbal consent script has been attached to this submission). Verbal consent will be documented in a secure REDCap database.

The research interviewer will then conduct an audio-recorded qualitative interview with research participants using the Guaranteed Income Control and Intervention Interview Guide (attached to this submission). Upon completion of the interviews, the qualitative interviewer will transcribe the interviews and upload transcription notes to a secure data server. The digitally recorded

interviews will then be professionally transcribed and loaded into NVivo software for data management and analysis.

Our scripted Mosio text messages have been attached to this submission. Participants will be compensated $35 for completing the in-depth interviews.

Baseline and 3-month study visits will occur in-person in a private room at 3535 Market Street at the Psychology of Eating and Consumer Health Lab at the University of Pennsylvania (PI: Roberto).

There will be no subject follow-up after the 3-month study visit and qualitative interview.

5.2. Consent

Randomized-controlled trial consent: Consent will be obtained from participants during the initial in-person visit, prior to the study session. A single consent will be used for all study activities except the qualitative interviews, which will involve a separate consent process. Assent will be confirmed prior to the follow up session. Participants will be provided a copy of the consent form, which will then be reviewed with the participant by study staff, and will only proceed with the study if they agree to consent. The consent form will be in English and will clearly state the purpose, eligibility criteria, study procedures, potential risks and benefits of participation, and the subject's right to refuse to participate or withdraw from the study. In particular, potential participants will be informed about the small impact on SSI benefits. We will provide information in the informed consent and welcome packet explaining that study payments are not considered countable income for the following list of government assistance programs, as well as information about how to report the income to ensure it does not affect eligibility:

- Temporary Assistance for Needy Families (TANF),
- Modified Adjusted Gross Income (MAGI) Medical Assistance (MA)
- non-MAGI MA including Home and Community-Based Services categories,
- Supplemental Nutrition Assistance Program (SNAP),
- Low-Income Household Water Assistance Program (LIHWAP),
- Low-Income Home Energy Assistance Program (LIHEAP).

It will be emphasized that participation in the study will not affect the right to care or services to which the potential participant would otherwise be entitled. It will be emphasized that only a subset of participants will be interviewed. Written consent will then be obtained and documented in REDCap.

Qualitative interview consent: Prior to conducting the interview, the interviewer will speak with participants on the phone and explain to participants that their participation is voluntary (see attached verbal consent script). The interviewer will also go over confidentiality and privacy with the participants. Participants will be informed that they can discontinue their participation at any time. The interviewer will answer any questions the participant has. Should the participant choose to participate in the study, the interviewer will document that they obtained verbal consent in REDCap.

6. Subject Compensation

All subject compensation will be through ClinCard.

All participants will receive $25 compensation for completing the baseline assessment, $50 for completing the follow-up assessment. Participants providing at-home blood pressure readings will also receive $3 per reading (maximum $3 per week, $48 total). Participants completing the in-depth interview will receive an additional $35.

Participants in the intervention arm will also receive $125 after completion of the baseline assessment, and an additional $125 every 2 weeks for 8 total payments ($1000 total).

7. Analysis Plan

AIMS 1 & 2: Data will be descriptively summarized and evaluated for quality prior to analysis. Means and standard deviations will be used to characterize continuous variables such as weight and blood pressure, and frequencies and percentages will be used to describe categorical variables. Medians and interquartile ranges will be reported for continuous variables that exhibit skewness. Data will be descriptively summarized overall and by condition.

All outcomes will be analyzed at the participant level. Analyses will employ population-averaged marginal models estimated by Generalized Estimating Equations (GEE) to account for correlations among the within-person baseline and follow-up measurements. Marginal models estimated by GEE are advantageous for their population-level interpretation and robustness of estimated effects to the assumed correlation structure among repeated measurements (meaning unbiased estimates of the effect of the behavioral intervention will be obtained whether or not the correlation among repeated measurements within a participant is modeled correctly). Clusters will be defined at the level of the participant for all analyses, and independence working correlation will be assumed. Linear models will be used for continuous outcomes and logistic models for categorical or ordinal outcomes.

Models will include intervention, measurement timepoint, and the interaction of intervention and measurement timepoint as categorical variables. The primary analysis testing the effectiveness of the cash transfers compared to the control arm will be evaluated by the test of the null hypothesis that the intervention-measurement timepoint interaction coefficient is 0, denoting no difference in the change in respective outcomes from baseline to month 3 between intervention and control. We will evaluate the sensitivity of estimated intervention effects to imbalances in baseline covariates and missing data. To assess the impact of imbalance in baseline covariates, outcomes will be reanalyzed in models that adjust for baseline covariates that differ significantly at the 0.05 level by condition. We will evaluate sensitivity to missing data by inverse probability of weighted GEE and multiple imputation. The Holm procedure at a family-wise error rate of 0.05 will be used to account for multiple comparisons in testing differences in 9 primary outcomes between the two groups (number of ED visits, number of non-ED visits, medication adherence, smoking, alcohol use, food security, utility security, health expenditures, and financial stress).

Aim 3 – Qualitative interviews: Qualitative analyses will be guided by an integrated approach that includes identification of a priori attributes of interest and identification of emergent codes and themes. A comprehensive coding scheme will be developed and applied to all data to produce a fine-grained descriptive analysis. All transcribed interview data will be imported into Nvivo for thematic coding. A single analyst will review and code all transcripts. The analysis will yield an understanding of any unanticipated or anticipated consequences of the study and cash transfer provision while also elucidating pathways through which cash transfers influence health behavior.

8. Investigators

This study will have the support of multiple PIs:

Christina Roberto, PhD, Associate Professor of Medical Ethics and Health Policy at the University of Pennsylvania

Aaron Richterman, MD MPH, Instructor of Medicine in the Division of Infectious Diseases at the University of Pennsylvania

Harsha Thirumurthy, PhD, Professor of Medical Ethics and Health Policy at the University of Pennsylvania

Co-investigators include:

Atheendar Venkataramani, MD PhD, Assistant Professor of Medical Ethics and Health Policy at the University of Pennsylvania

Heather Schofield, PhD, Assistant Professor of Medical Ethics and Health Policy at the University of Pennsylvania

Laura Gibson, PhD, Research Assistant Professor of Medical Ethics and Health Policy at the University of Pennsylvania

Ayiti-Carmel Maharaj-Best, MD, Assistant Professor of Family Medicine and Community Health at the University of Pennsylvania

9. Human Research Protection

The team includes investigators experienced in clinical medicine, health behavior interventions, economic interventions, clinical trials, behavioral economics, and program evaluation.

9.1 Data Confidentiality

- Paper-based records will be kept in a secure location and only accessible to personnel involved in the study
- Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords
- Only 4 members of the research team will have access to the dataset exported from the EPIC report created through SlicerDicer, which contains MRN
    - Laura Gibson, Analyst
    - Aaron Richterman, PI
    - Christina Roberto, PI
    - Eva Fabian, PM
- Wherever feasible, identifiers will be removed from study-related information
- Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects

9.2 Subject Confidentiality

Aaron Richterman is a UPHS physician with access to SlicerDicer who has completed SlicerDicer research training through Penn Knowledge Link. He will be generating the eligibility dataset on SlicerDicer and exporting the data to an EPIC Report using the IRB-approved protocol number. He will send recruitment MyPennMedicine messages directly through EPIC to potential participants on this report. He will also download this dataset as a .csv file onto a UPHS Computer, and this dataset will be uploaded onto REDCap for the team to use during follow-up of people completing the interest form, to assess for eligibility.

Data will be entered directly on encrypted University of Pennsylvania computers into the web-based password-protected REDCap database. Collected Protected Health Information (PHI) will include the following: Name, address (for the purpose of ClinCard compensation), zip code, telephone number, and social security number (for the purpose of ClinCard compensation). Participants will automatically be assigned a study ID through the REDCap system. When records are complete, data will be downloaded from the web-based system with the generated study ID. Protected Health Information (PHI) will be delinked from the data and inaccessible to all study staff aside from the Investigators. At the end of the study, a list of MRNs for consented study participants will be submitted in a DACS request to obtain their active problem list, medications history, and visits (office, ED, hospital) 3 months before and after their study start date. This limited dataset will be used for analysis and will be maintained on an encrypted and password-protected University of Pennsylvania server accessible only to the Investigators.
Qualitative interviews: Audio recordings of interviews will be uploaded securely for transcription after sessions have been completed. Transcripts will be identifiable only through the participant identification number assigned for the purposes of the research. Only the study team will have access to these transcripts. Once all analysis and write up is complete, the interview transcripts will be destroyed. The data will not be distributed for future research studies. Transcriptions will be linked to the remainder of the study data through the study ID, and any identifying information inadvertently collected during recording will be immediately deleted from the transcripts. Transcripts will be stored in an electronic NVivo database on fire-walled servers accessible only to authorized project personnel.

Patient identifiers will be destroyed.

9.3 Subject Privacy

Privacy will be maintained through use of private rooms for the consent process and study procedures. ClinCards will be used for subject compensation and for the intervention — as ClinCards are commonly used for many kinds of research studies, they will not identify participants as recipients of a cash benefit. W9 and C2 forms will be collected for all participants during their enrollment period. These forms will be filled out on paper and stored in a secure location in the research office. W9 forms will be shredded at the end of the study once entered in the Greenphire W-9 database.

9.4 Data Disclosure

Data may be disclosed to The Office of Human Research Protections at the University of Pennsylvania, federal and state agencies (for example, the Department of Health and Human Services, the National Institutes of Health, and /or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/ or necessary for oversight purposes.

Otherwise, data will not be disclosed to anyone who is not listed under study personnel.

Protected Health Information/ Data Protection

- **Name**
- Street address, city, county, precinct, **zip code**, and equivalent geocodes
- **Telephone** and fax number
- **Social Security Number**

Genetic testing

N/A

CONSENT

Consent Process, Children and Adolescents

Not applicable. We are only enrolling subjects 18 years of age and older

9.5 Data Safety and Monitoring

Our Study Safety Officer, Dr. Ronald Collman, will be responsible for monitoring the data safety and quality and ensuring that all relevant IRB policies, procedures, and stipulations are followed. These responsibilities will include ensuring that other investigators and project staff adhere to the IRB regulations and policies including processes for: (1) obtaining informed consent; (2) informing participants how to contact the PI, study coordinator, or IRB office with questions and/or concerns; (3) strictly adhering to a participant's right to withdraw from the study or decline to answer questions; (4) maintaining participant confidentiality and data de-identification processes; (5) securely storing data; (6) submitting any amendments to the IRB for approval prior to implementing changes to the protocol; and (7) monitoring and reporting adverse events.

9.6 Risk/Benefit

9.6.1 Potential Study Risks

As this study does not involve changes to standard patient care or medical decision making, we consider this study minimal risk. The primary risk is a breach of confidentiality. This risk has been mitigated by extensive privacy protection protocols, a highly secure data storage system, and a plan to remove identifiers from the data wherever possible. In addition, all personnel will be held to high standards of upholding confidentiality and safeguarding patient privacy.

In addition, for participants receiving the intervention there is the risk that the Social Security Administration (SSA) may decide that participants receiving Supplemental Security Income (SSI) benefits have been slightly overpaid during the four months of the study. SSA may ask them to return the overpayment, but should not (by themselves) affect their eligibility for SSI Benefits. Participants may ask SSA to waive recovery of the overpaid money by going to their local Social Security office. Our team has received correspondence (attached to application) from the state of Pennsylvania confirming that study payments are not considered countable income for the following government programs, and therefore will be no loss to these benefits:

- Temporary Assistance for Needy Families (TANF),
- Modified Adjusted Gross Income (MAGI) Medical Assistance (MA),

- non-MAGI MA including Home and Community-Based Services categories,
- Supplemental Nutrition Assistance Program (SNAP),
- Low-Income Household Water Assistance Program (LIHWAP), and
- Low-Income Home Energy Assistance Program (LIHEAP).

Low-income individuals will address their experiences with poverty and receipt of short-term cash transfers. These can be sensitive topics and may cause some minor distress. These participants will be offered a referral list for social services resources designed to provide financial support.

9.6.2 Potential Study Benefits

The direct benefits of this study for participants in the intervention arm may include improvements in health outcomes. It is possible, however, that the benefits for these participants will be minimal. The control group is unlikely to directly benefit, as this group will continue to simply receive usual care. Participants may benefit indirectly through the knowledge gained in this study, which could assist in the development of interventions to improve health outcomes for people with chronic diseases.

9.6.3 Alternatives to Participation

Patients are free not to participate in this study and non-participation will result in no change in the usual care received from their health care providers.

9.6.4 Risk/ Benefit Assessment

Because this study does not pose more than minimal risk for study participants, we believe the benefits of this study outweigh the risks involved.

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