Pilot Guaranteed Income (PGI) Analysis Plan

June 6, 2023

NCT05838027

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Instructions
The Analysis Plan differs from the AsPredicted in that we expect analysts to update it at important milestones:
1. Beginning analysis X
2. Submitting draft to journal
3. Submitting revision to journal
4. Accepted paper to journal

Paper 1: covers Aims 1 and 2 (i.e., everything except qualitative data)

Aim 1: To 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) & Aim 2: Assess potential psychological mechanisms through which the intervention influences cardiovascular health (Stage 0, research on mechanisms of change)

Dataset

Sample: Survey and measurement data from 100 participants at baseline and 3-month follow-up in a two-arm randomized controlled trial (50 in control, 50 in intervention). Participants are adult patients at UPenn Family Care on Medicaid with either a prediabetes, diabetes, or hypertension diagnosis who have received care there in the past 6 months, live in the greater Philadelphia area, and are actively prescribed oral medication for diabetes or hypertension. Participants will be recruited using UPenn Family Clinic EHRs. Initial interest data will be collected via a REDCap online survey. Most other data will be collected through REDCap surveys completed in-person at the baseline and 3-month visits. Participants' blood pressure and height and weight measurements will also be taken at these visits, and participants will complete a psychomotor vigilance task as well as a behavioral snack choice. 16 participants will receive a blood pressure cuff to take home and send measurements weekly (for 16 weeks; 8 control, 8 intervention; half of each group will transmit wirelessly, the other half won't). These participants will be texted REDCap surveys to fill out weekly with blood pressure measurements. Finally, participant EHR data will be pulled for the 3 months prior to their baseline measurement and 3 months after matched on name and birthdate.

Intervention: In the unconditional cash transfer intervention, participants will receive $125 every 2 weeks for 8 payments via ClinCard, for a total of $1000.

Primary Outcome: Our 8 primary outcomes for this pilot study are:
1. food security (3-category, US Dept of Agriculture) (Aim 1)
2. utility security (5-category; Home Energy Insecurity Scale) (Aim 1)
3. financial well-being scale (0-100, Consumer Financial Protection Bureau Financial Well-Being) (Aim 1)
4. Perceived Stress Scale (0-16, short form) (Aim 2)
5. state anxiety scale from the State Trait Anxiety Inventory (standardized score as per the manual) (Aim 2)
6. number of lapses in the Psychomotor Vigilance Task (Aim 2)
7. health care expenditures on medications (raw dollars) (Aim 1)
8. adherence to medication refills subscale (4-16; Adherence to Refills and Medications Scale (ARMS)) (Aim 1)

Aim 1 = Specific health behaviors
Aim 2 = Potential psychological mechanisms

Covariates: 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 study arm. These include:
- Sociodemographics: age, sex, gender, low-income vs other-income zipcode, race, ethnicity, sexual orientation, marital status, schooling attainment, being a parent, number of children
- Economic data: work, income sources (including government programs such as SNAP, TANF, and WIC), and total household income
- Housing data: living situation, household composition, and housing security
- Number of chronic medications
- Chronic medical conditions (problem list) – especially the 3 inclusion criteria: prediabetes, diabetes, and hypertension

Potential Moderators: In exploratory analyses, to examine whether the intervention impacts health inequities within the sample population, we will assess the intervention effects on physical and mental health across several sociodemographic categories (as tested in Jaroszewicz et al, 2022 RCT with 5,243 participants; $500 or $2000 one-time transfers (participant median monthly income = $1000)).
- Gender (binary: female)
- Race (binary: not exclusively white)*
- Age (continuous)
- SES
    - Household income level as % FPL (continuous)
    - Yost SES Quintile (binary: lowest vs other; factor analysis of 7 ACS variables; used by SEER; instead of ADI based on Boscoe et al, 2021)
    - Income sources (binary: received governmental assistance at baseline)
    - Work (binary: being employed at baseline)

- o Schooling attainment (binary: completed at least high school)
- Family structure
  - o Being a parent (binary)
  - o Number of children (continuous)
  - o Fraction of one's children who are male (proportion)*
  - o Marital status (binary: having a partner or spouse)*

Data Analysis
Primary Statistical Methods & Software: 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 independent working correlation will be assumed. Linear models will be used for continuous outcomes and logistic models for categorical or ordinal outcomes. Analyses will be conducted using Stata.

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. The Holm procedure at a family-wise error rate of 0.05 will be used to account for multiple comparisons in testing differences in the 8 primary outcomes between the two groups.

Exclusion Criteria & Restrictions: Physician co-investigators will clarify any values that appear out of range (e.g., biologically implausible values) prior to excluding any data. Any data that are excluded will be done prior to re-matching participants to study arm.

Assumption Checking & Data Cleaning: Data will be descriptively summarized and evaluated for quality prior to analyses. 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 study arm.

As a manipulation check, we can also download the Clincard data to see how much money is left on people's cards at the end of the study.

Missing Data: Although we expect to have minimal missing data because most questionnaire items are required, we will consider other analytic techniques like inverse probability of weighted GEE and multiple imputation to handle missing data (e.g., due to loss to follow-up) if the amount is greater than 10%.

Secondary Analyses: *[Could be subgroup analyses, sensitivity analyses, exploratory analyses]*
- If there is enough variation in moderators, exploratory moderation analyses will test how they impact the main effect. Given the pilot nature of this study, we will focus first on household income % of the federal poverty line, but other moderators will be considered.

- Our 10 secondary outcomes include:
    1. number of Emergency Department (ED) visits (from the Electronic Health Record (EHR))
    2. number of non-ED visits (EHR)
    3. smoking (5-25, Cigarette Dependence Scale, short version (CDS-5))
    4. alcohol use (0-12, Alcohol Use Disorders Identification Test (AUDIT-C))
    5. all health care expenditures (raw dollars, medications + office visits + ER visits)
    6. time preference: patience item (0-10)
    7. time preference: behavioral choice task (binary)
    8. Kessler Psychological Distress Scale (6-30, K6+)
    9. self-reported number of healthy days from (CDC health-related quality of life HRQOL-4)
    10. medication taking adherence subscale (ARMS)

- Exploratory health outcomes include objectively measured body mass index and systolic and diastolic blood pressure.
- Secondary analyses of medication adherence will compare the self-reported medication adherence refills (ARMS) to EHR frequency of medication refills (i.e., combining medication name, recommended frequency of use, quantity prescribed, number of refills per prescription, and refill start date) as a proxy for adherence. Note: Refills are requested by pharmacies or patients, so pharmacy refill requests could bias toward adherence.
    - If there is a strong relationship between the ARMS and the EHR prescription measure, we will analyze the EHR prescription measure as a secondary outcome.
- We will assess whether the Acceptability of Intervention Measure (4-item mean, 1-5) varies by any demographic characteristics.

Table Shells: *[Not required to include these, but they may help focus the analysis plan, or help get the paper started]*

References
- Boscoe FP, Liu B & Lee F. (2021). A comparison of two neighborhood-level socioeconomic indexes in the United States. *Spatial and Spatio-temporal Epidemiology, 37.* http://dx.doi.org/10.1016/j.sste.2021.100412
- Jaroszewicz A, Jachimowicz J, Hauser O & Jamison J. (2022). How effective is (more) money? Randomizing unconditional cash transfer amounts in the US. Available at SSRN: https://ssrn.com/abstract=4154000 or http://dx.doi.org/10.2139/ssrn.4154000

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