Unstable Income, Rising Stress?

The Effects of Income Instability on Psychological and Physiological Health

National Clinical Trial (NCT) Identified Number: Currently N/A

Principal Investigator: Heather Schofield

Sponsor: Cornell University

Grant Title: Unstable income, Rising Stress? The Effect of Income Instability on Psychological and Physiological Health

Grant Number*: R01AG076655

Funded by: National Institutes of Health (NIH) in the United States

Version Number: v.1.0

23th July 2024

CONFIDENTIALITY STATEMENT

This document is confidential communication. Acceptance of this document constitutes agreement by the recipient that no unpublished information contained herein will be published or disclosed without prior approval of the Principal Investigator or other participating study leadership and as consistent with the NIH terms of award.

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STATEMENT OF COMPLIANCE

(1) The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

The IRB of record in the United States is the University of Southern California (FWA 00007099) under protocol number 6708.

Additionally, Cornell University (FWA 00004513) has entered into a reliance agreement with USC.

The Ghana Health Services IRB has also approved this protocol (GHS ERC number: 016-03-23).

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed: Heather Schofield Date: 3/25/2024

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1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title: The Impacts of Predictable Income Volatility and Income Risk on Economic Outcomes and Behaviors

Grant Number: 1R01AG076655

Study Description: To explore the relationship between income stability and health, we will run a randomized experiment in northern Ghana. To accomplish this goal, the study will provide temporary employment for low-income individuals during the lean season, when work is scarce. Participants will be randomly assigned to one of the four arms which vary whether the number of work hours vary over time and whether they vary predictably or unpredictably. The study will enroll 2,267 participants for 12 weeks (i.e. 6 periods) with an additional follow-up survey occurring 4 weeks after the conclusion of the active study phase. We hypothesize that all treated participants will experience gains in mental health relative to the control (given the increased income), but that the gains will be largest among the arm receiving stable and predictable work and lowest in the arm receiving unstable and unpredictable work.

Objectives*:

Primary Objective:

1) Identify the causal effect of income instability on psychological health (e.g. depression, anxiety), biomarkers of stress (e.g. cortisol), and physical health (e.g. blood pressure).

Secondary Objectives:

1) Decompose the effects identified in aim 1 into the effects of predictable and unpredictable income instability and compare them to the impact of increasing the average level of income.
2) Investigate the channels through which effects on health occur, including both economic and behavioral channels and estimate the impact of key moderating factors (e.g. age, gender, baseline mental health).

Endpoints*:

Primary Endpoint:

1) Depression
2) Anxiety
3) Stress – cortisol
4) blood pressure
5) dietary diversity and sufficiency

Secondary Endpoints:

1) Stress – self-reported
2) Worry
3) Subjective-wellbeing
4) Weight

Study Population:

The study will take place in communities/districts around Tamale in the Northern Region of Ghana. A random sample of households will be surveyed in approximately 135 villages to identify eligible participants.

Individuals will be eligible if they are between the ages of 18 and 65. Only individuals of legal age to work will be enrolled to ensure compliance with local laws. Further, restricting the sample to adults ensures all participants are able to provide informed consent. We restrict the sample to those 65 and under given the nature of the work and the need to commute to the worksite. Given the nature of the work (sewing) and local gender norms, we will enroll women into the study. We will also exclude women who are pregnant as pregnancy and the post-partum period are often associated with depression unrelated to one's work environment (and hence less likely to be impacted by our treatments). However, no participants will be dropped from the study if they become pregnant during their participation and wish to continue. Finally, to guarantee that the data collection is feasible within short time windows, large households, with many working adults, will not be eligible to participate in the study. The randomization will be conducted to ensure that there will only be one participant per household. 2,267 eligible participants will be randomly assigned to one of the four conditions described below. sample size, gender, age, demographic group, general health status, and geographic location.

Phase* or Stage:

Stage 3

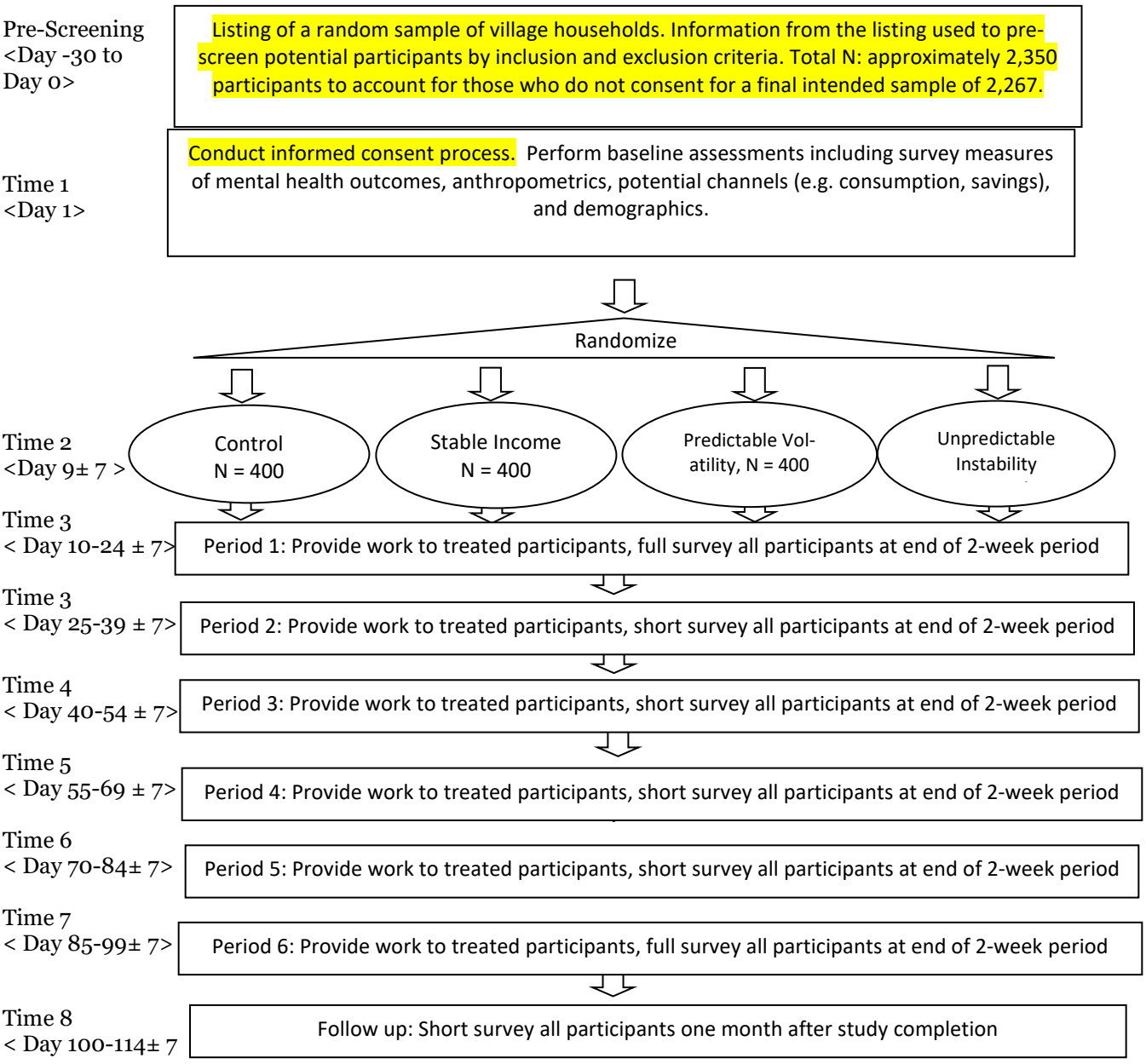
Description of Sites/Facilities Enrolling Participants:

IPA-Ghana will screen and enroll participants into the study, with operations based from their office in Tamale, Ghana. IPA-Ghana has collaborated on over 60 studies with tens of thousands of participants in Ghana since its founding in 2009, including a number of trials considering mental health.

Description of Study Intervention/Experimental Manipulation:	Individual participants will be randomly assigned to one of four study arms: 1) The Control Arm: The Control arm will not be hired by the cash-for-work program but will be surveyed; 2) The Stable Income Arm: The Stable Income arm will work the same number of days and earn the same amount every two-week period; 3) The Predictable Instability Arm: The work days and earnings of the Predictable Instability arm will vary over time. In three periods, the participant will work more days and will earn more. In the remaining three periods, she will work fewer days and will earn less. Crucially, she will be able to predict all swings in her study earnings in the future—i.e., she will know her work days and earnings in each future two-week period. 4) The Unpredictable Instability Arm: The work days and earnings of the Unpredictable Instability arm will vary unpredictably over time. In any given two-week period, there will be a 50% chance that she works more days and earns more and a 50% chance that she works fewer days and earns less. Work opportunities will be provided for 12 weeks, during which participants will be able to choose the total amount of labor they supply to the work program. The delivery of the intervention is in-person.
Study Duration*:	Face-to-face interviews conducted at the participant's home will be conducted at baseline and the end of the intervention. We expect that these surveys will take about 1-2.5 hours. In addition, we will conduct brief phone surveys 2, 4, 6, 8, and 10 weeks after the start of the intervention and a final one 4 weeks after the end of the intervention. The phone surveys should take approximately 20-30 minutes.
Participant Duration:	The total length of subject participation will be 4-5 months from the screening survey through the follow-up.

1.2 SCHEMA

Flow Diagram



1.3 SCHEDULE OF ACTIVITIES

Day -30 to -1		Day 0	Day 10-14	Day 24-28	Day 38-42	Day 52-56	Day 70-74	Day 80-100	Day 98-102
			End of period						4 weeks later
Screening and randomization		Baseline	2	3	4	5	6		
	Demographics	Full						Qualitative debriefs for subset of participants	
	Economic measures	Full	Short	Short	Short	Short	Full		Short
	Psychological wellbeing (Depression, Anxiety, Stress via cortisol and self report, worry, subjective-wellbeing)	Full	Short	Short	Short	Short	Full		Short
	Physical health (blood pressure, dietary diversity and sufficiency, weight)	Full					Full		Short
	Adverse event reporting	X	X	X	X	X	X	X	X

Participants will be surveyed at Baseline, the end of every 2-week period, and 4 weeks after the end of the active intervention. The Baseline and post period 6 survey are in person and more extensive (lasting roughly 2-2.5 hours). All remaining surveys are telephonic and last roughly 20-30 minutes. Treated participants will additionally be offered work throughout Days 0-74 according to their experimental arm and randomized draws.

Ethical reviews (detailed in section 1) have been completed. We anticipate beginning the pilot study in late April 2024 and the full study in April of 2025. Within each of these studies, the timeline will proceed as detailed in the table above. Following the completion of the RCT in the summer of 2025, we will assay the cortisol samples, analyze the data, write manuscripts, and disseminate results in 2025-2026.

2 INTRODUCTION

2.1 STUDY RATIONALE

The poor are known to suffer disproportionally from poor mental and physical health. Many causes for these disparities have been considered, including low income. Yet, poor families' incomes are not only low, but also often unstable and unpredictable (Collins et al. 2009). Income instability creates uncertainty about whether they will be able to safeguard their future wellbeing: *Will they have enough money to put food on the table*? *To pay for rent*? *To pay for a doctor's visit*? (Jolliffe and Ziliak 2008; Bhattacharya et al. 2004) The allostatic load framework posits that, if uncertainty (of any type) is not resolved, prolonged activation of physiological stress responses will cause "wear and tear" on the body, heightening risks of cardiovascular disease and of age-related metabolic diseases, promoting cognitive decline and dementia, and accelerating cellular aging (Peters et al. 2017). Income instability could therefore increase the rate of aging among the poor and contribute to disparities in physical and psychological health.

While many researchers have studied the effects of the level of income on health, causal evidence on the impact of income instability – both in terms of predictable and unpredictable fluctuations – on health and aging is lacking (Prause et al. 2009; Kim and Subramanian 2019). Previous work on income instability did not study anxiety, stress, and worry — the aspects of psychological health thought to be affected by uncertainty (Carleton et al. 2007; MacLeod et al. 1991; de Berker et al. 2016) — and was not restricted to the poor, who are more likely to be impacted by income instability. Further, isolating the effects of income instability is empirically challenging. First, to isolate its effect, one needs to vary income instability while holding the average level of income constant; an uncommon occurrence in naturally-occurring data. Second, it is difficult for the researcher to know which shifts were predictable to the individual experiencing them. Finally, there may be many other differences between individuals with different degrees of income instability. For example, they may have different occupations, different tolerance for risk, or different expenditure patterns. These empirical challenges make it extremely difficult to study the causal effects of income instability using observational data.

This R01 will study the causal effects of income instability on the psychological and physical health of the poor as well as on biomarkers of stress via a randomized controlled trial. We will conduct an experiment in northern Ghana that will manipulate income instability by varying the number of work hours (and hence the earnings) of participants in a cash-for-work program. Similar to many low-income countries, most workers are primarily employed in casual labor with highly unpredictable and unstable incomes (ILO 2016). Participants in the first treatment arm (Stable Income) will have a fixed work schedule, with the same hours and earnings each period. The hours and earnings of a second treatment arm (Predictable Volatility) will vary over time, but the fluctuations will be known in advance. Finally, the number of work hours and earnings of a third treatment arm (Unpredictable Instability) will fluctuate unpredictably. Each of these arms will be compared to a control group (Control) that is surveyed, but not offered additional work. Importantly, we will vary income instability while holding the average level of income constant in order to disentangle the impact of instability from the level-effect.

We will collect the extensive data detailed in the outcomes section – including data on mental and physical health as well as potential economic channels – to assess the impacts of income instability on these outcomes and the paths through which they operate.

2.2 BACKGROUND

Health disparities by socio-economic status remain prevalent both within and between countries (Bor et al. 2017; Chetty et al. 2016; Lopez and Marray 1998; Global burden of disease study 2020). Such disparities are not limited to physical health, but also extend to psychological health (e.g., Costello et al. 2003; Lund et al. 2010) and physiological aging (e.g., Seeman et al. 2004, 2010; Robertson et al. 2013). Income levels are a clear driver of such disparities, with numerous studies documenting a strong relationship between income and health (e.g., Vogl et al. 2008; Ridley et al. 2020; Bleakley 2010; Pickett and Wilkinson 2015). Yet, one underappreciated feature of the lives of the poor is that their income is not only low, but also unstable and uncertain (Bania and Leete 2009; Morris et al. 2015; Hannagan & Morduch 2016). According to the "Portfolios of the Poor", a canonical book describing the finances of the poor, *"[o]f all the commonalities [among poor households], the most fundamental is that the households are coping with incomes that are not just low, but also irregular and unpredictable*" (Collins et al 2009). This pattern is common to both low- and high-income countries and impacts a wide range of workers from farmers to delivery drivers (Morduch and Schneider 2017).

Income instability makes it harder for the poor to make ends meet. Because the poor often lack a cushion of savings and have limited access to credit, when income dips, they may have no alternative but to reduce their consumption, leading consumption to fluctuate with income (Dercon 2002; Gorbachev 2011; Dorga and Gorbachev 2016). These downward swings may have drastic consequences. The poor may have to skip meals – generating food insecurity, or forgo medical care – impairing health. Even if the poor manage to shield consumption against income fluctuations, income instability may still be harmful if consumption stability is achieved by selling productive assets or taking high-cost debt (Chetty and Looney 2006; Rosenzweig and Wolpin 1993). Further, shielding consumption from income fluctuations may be particularly challenging when the fluctuations in income are unpredictable, which is often the case among low-income households.

Income instability may also harm the psychological health of the poor. The uncertainty about whether and when income will dip and if and how they will manage to make through may cause anxiety, worry, and stress (Dobridge 2018; Carleton et al. 2007; MacLeod et al. 1991; De Berker et al. 2016). The prospect of deprivation experienced when income dips is a threat. Anxiety is a response to a potential threat about which there is uncertainty (Carleton et al. 2007). Uncertainty also underlies worry, defined by MacLeod et al. (1991) as a cognitive phenomenon "*concerned with future events where there is uncertainty about the outcome."* Similarly, the uncertainty about whether one will be capable of coping with such a change in environmental demands may cause stress (Cohen et al. 1997).

The uncertainty associated with income instability may ultimately accelerate cellular aging and the progress of age-related diseases. In "Uncertainty and Stress: Why it Causes Diseases and How it is Mastered by the Brain" (Peters et al. 2017), Bruce McEwen and co-authors argue that stress arises when one is uncertain about how to safeguard one's future physical, mental, and social wellbeing and that this stress in turn burdens the body with "allostatic load", "the wear and tear on the body" that accumulates as an individual is exposed to repeated or chronic stress (McEwen & Stellar 1993). When acute stress responses are insufficient for resolving uncertainty, "the neuroendocrine, cardiovascular, neuroenergetic, and emotional responses become persistently activated so that blood flow turbulences in the coronary and cerebral arteries, high blood pressure, atherogenesis, cognitive dysfunction and depressed mood accelerate disease progression" (Peters et al. 2017, p.167).

This reaction may cause a vicious cycle as one ages. The glucocorticoid cascade hypothesis argues that aging causes degenerative changes in the region of the brain responsible for shutting off the

stress response (Sapolsky et al. 1986). When this response is not promptly turned off, it causes further damage to the brain. Hence, uncertainty could trigger a circular process where stress accelerates aging, in turn damaging an individual's capability to cope with the effects of uncertainty, further exposing her to the effects of allostatic load (Peters et al. 2017).

While income instability is central to the lives of the poor and may impact many aspects of their health, relatively little is known about this relationship. The bulk of the literature considering health disparities between the rich and the poor has focused on the level of income rather than its instability and unpredictability (e.g., Costello et al. 2003; Lund et al. 2010; Seeman et al. 2004, 2010; Robertson et al. 2013). One exception is Prause et al. (2009), which studies the association between income volatility and depression using data from the National Longitudinal Survey of Youth (BLS 2019) data. Prause et al. find a positive correlation between income volatility and depression, though the relationship dissipates when controlling for average income. Evidence also exists for a correlation between income volatility and cardiovascular disease (Elfassy et al. 2019) and mortality (e.g., Sullivan & von Watcher 2009; Bævre & Kravdal 2014; Elfassy et al. 2019). Studies have also shown that health insurance – which reduces volatility in expenditures – is linked to reduced depression, stress, and cortisol levels (Baicker et al. 2013; Haushofer et al. 2020). Yet, the provision of healthcare could also be driving these effects. Despite this related work, we are not aware of any work that has isolated the relationship between income instability and anxiety, worry, or stress—the specific dimensions of psychological health expected to be affected by economic uncertainty. In short, our knowledge of the association between income instability and health is still limited. As Holt (2016) writes, "*[d]espite the efforts of scores of researchers, there is no consensus on the extent of [income] volatility and how it affects individual well-being, especially among vulnerable low- and moderate-income populations*."

Advancing our understanding of the relationship between income instability and health is crucial to reducing health disparities between the rich and the poor. As discussed in greater detail below, this gap in knowledge is driven in part by the challenges in using observational data to study the effects of income instability. First, it is not possible to distinguish between income swings which are known in advance from those which are unpredictable. Second, if the income of individual A fluctuated more in the past than the income of individual B, the researcher cannot tell whether A had greater variability than B and already expected her income to be more unstable than B's, or if their incomes were expected to be equally uncertain but A's ended up by chance fluctuating more than she expected (Alem & Colmer 2018). Third, there may be other differences between these individuals (e.g. in risk preferences) that confound the relationship between income instability and health. Finally, much of the work to date has not focused on the poor, the group most likely to be impacted by instability and uncertainty (Prause et al. 2009; Sullivan & von Watcher 2009; Bævre & Kravdal 2014; Elfassy et al. 2019).

We will conduct a randomized controlled trial which will allow us to overcome these challenges and estimate the causal impact of income instability on health. The study will take place in northern Ghana where a cash-for-work program offers temporary employment during the lean season when little work is typically available. We will generate exogenous variation in income instability by varying the number of hours for which study participants are hired over time and whether these fluctuations in the number of work hours are communicated in advance and hence predictable. We will study the causal effects of income instability on psychological health (e.g. depression, anxiety), biomarkers of stress (e.g. cortisol), and physical health (e.g. dietary sufficiency). We will further decompose the effects identified in aim 1 into the effects of predictable and unpredictable instability and compare them to the impact of increasing the average level of income. Finally, we will gather extensive data on potential moderators (e.g. gender, age, baseline health) and mediators (e.g. economic channels such as savings and asset sales) to investigate the channels through which effects on health occur.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

Risks Associated with Experimental Activities

As there are no changes to the lives of control individuals except their participation in brief surveys, the risks associated with control condition are no more than minimal and are similar to the ones in participants' everyday life. Treated participants will additionally work in the cash-for-work program, facing potential psychological and physical risks.

- *Psychological risks* - we will proactively be screening all participants (both control and treatment) for poor mental health via the twice-monthly surveys. Any individuals scoring at or above the thresholds for depression recommended by Dr. Lund, individuals who scores have increased beyond a threshold since baseline, or those expressing suicidal ideation, will be contacted by phone and asked if they would like to avail themselves of telephonic counseling with counselors provided by local NGOs. Again, those thresholds are a PHQ-2 score of six or a score increase of more than 2 relative to baseline. The counseling sessions are free whether or not a participant decides to continue participating in the study. In rare cases when a participant indicates thoughts of suicide, self-harm, or harm to others, Mind 'N' Health has an action protocol to, first, collect relevant details on the situation for assessment and, then, initiate follow-up actions with Ghana Health Services including in-person services at local government-run health facilities. With the participant's consent, Mind 'N' Health will also work with the individual's family to facilitate access to these additional services.

Physical risks - The sewing work provided has some risk of injury (e.g. sticking one's finger with a sewing needle), however this risk is likely lower and certainly no more than the risks faced by these individuals in other jobs (e.g. agricultural labor, collecting firewood). Surveys will also be conducted outdoors weather permitting and many dwellings are open-air. Hence, the intervention is not likely to significantly alter Covid-19 exposure.

For AEs and SEAs related to health, participants will be referred to the closest government health post or hospital, depending on the severity of the event. The costs of transportation for AEs and SEAs considered related or potentially related to study participation will be covered by the study.

Risks associated with privacy

There is a potential risk of survey answers not being kept confidential, which would violate the privacy of respondents. However, we take numerous steps to protect respondents' privacy and minimize any risk that confidentiality is broken. Overall, we believe these risks are minimal and no more than those faced in everyday life.

We do not foresee any long-term risks from participation in the study.

2.3.2 KNOWN POTENTIAL BENEFITS

The study will create new jobs that would not otherwise be available. This constitutes a direct benefit to participants and their families, especially as it will come during a season of deprivation. Participants will be informed that participation is voluntary and may choose not to avail themselves of the work with no penalty or loss of other benefits to which they are entitled. The intervention has been designed so that the job opportunity cannot make them worse off than they would otherwise have been in the absence of research. Further, participants will be trained on a skill – sewing – that they otherwise would not have. Generating the potential to find future employment (or self-employment) opportunities.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

The risks of the additional work are unavoidable as the effects of earned and unearned income may be quite different and earned income is significantly more policy-relevant. In addition, the risks to privacy are required in order to gather the data that is needed to assess the study.

The physical risks associated with the work have been minimized by choosing work that is unlikely to cause injury (stitching bags). The psychological risks have been minimized via active monitoring and referral processes as well as the increase in available in work among all treated participants prior to introducing variation or uncertainty. Because participants can always choose to not undertake any of the offered work, they can not be made worse off than in the absence of the offer. Notably, we have worked with an ethicist who specializes in participant payment/compensation – Dr. Emily Largent (UPenn) in designing this study to ensure it meets the highest ethical standards. Finally, the privacy risks have been minimized by collecting only the needed data and developing robust data-security protocols focused on privacy and security.

The value of participation outweighs the risks because income instability is a fundamental concern in the lives of the poor. Understanding the full costs of this phenomenon would better allow policymakers to develop and promote policies to address the concern. These substantial benefits are weighed against relatively low risks to participation given the design considerations outlined above.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
Identify the causal effect of income instability on psychological health, biomarkers of stress, and physical health.	Depression (PHQ) Anxiety (GAD) Stress (cortisol) Blood pressure Dietary diversity and sufficiency	Depression, Anxiety, and Stress are three key elements of mental health that are likely to be impacted by income volatility and uncertainty. Blood pressure is a potential downstream consequence of such stress. Dietary diversity and sufficiency are key proxies for the likely long-term impacts of instability and uncertainty on physical health via nutrition.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Secondary		
1) Decompose the effects identified above into the effects of predictable and unpredictable income instability and compare them to the impact of increasing the average level of income. 2) Investigate the channels through which effects on health occur, including both economic and behavioral channels and estimate the impact of key moderating factors.	The endpoints for (1) are the same as the primary objective. The analysis varies by looking at the underlying drivers rather than the overall impacts. Additionally, we will examine other elements of mental health and well-being including stress (self-reported), worry (Penn State), Subjective well-being (Cantril and Deiner's), absolute weight, and relative weight change (in kg and percent change. Endpoints for (2) include measures of income and consumption dynamics (e.g., savings/debt, transfers, consumption, and additional labor supply) and key demographics (e.g. age, gender, baseline mental health)	Endpoints for (1) are outcomes. Endpoints for (2) are mediators and moderators.

4 STUDY DESIGN

4.1 OVERALL DESIGN

The study will consist of a 4- arm phase-3 randomized controlled trial to avoid concerns around the measurement and endogeneity of income streams and participants knowledge of those income streams. We hypothesize that the impact of the treatments on our primary endpoints will be positive overall (due to the increased work and income), but that the Stable Income will have the largest treatment effects, the Predictable Volatility arm the next largest, and the Unpredictable Instability arm the least (though still positive relative to the control).

The randomization will be at the individual level, stratified by village. Participants will be randomized among 4 arms:

1) The Control Arm: The Control arm will not be hired by the cash-for-work program but will be surveyed;

2) The Stable Income Arm: The Stable Income arm will work the same number of days and earn the same amount every two-week period;

3) The Predictable Instability Arm: The work days and earnings of the Predictable Instability arm will vary over time. In three periods, the participant will work more days and will earn more. In the remaining three periods, she will work fewer days and will earn less. Crucially, she will be able to predict all swings in her study earnings in the future—i.e., she will know her work days and earnings in each future two-week period.

4) The Unpredictable Instability Arm: The work days and earnings of the Unpredictable Instability arm will vary unpredictably over time. In any given two-week period, there will be a 50% chance that she works more days and earns more and a 50% chance that she works fewer days and earns less.

Randomization will be done using statistical software for the treatment assignments and a process of drawing sealed envelopes for the period-by-period realizations in the Unpredictable Instability arm (to increase trust in the randomization process). The Control, Stable, Predictable Volatility arms will each have 400 participants. The Unpredictable Instability arm is overweighted with 1,067 participants, as the analysis of this arm will be disaggregated depending on the draws realized by each participant. The participant will learn of their study arm assignment after consent and the baseline survey, but prior to the beginning of the first 2-week period. The PIs and associated staff under their direction will generate the randomization code and output, with the exception of the period-by-period draws for the Unpredictable Instability participants which will occur in the field.

Unpredictable Instability participants will realize their draw for the next period in the five days between the time when the work for the prior period is completed and the work for the next period begins. This randomization is assured to be truly random via the following procedure:

- The field officer arrives at the participant's house with two sealed envelopes. One contains a "high" draw and the other a "low" draw for the period, as indicated by a work calendar. Both have the participant's ID number on the outside of the reverse (sealed) side of the envelope.
- The participant selects and opens one envelope
- The field officer photographs the calendar from the open envelope in the same frame as the sealed envelope with the same participant ID. This ensures that we can verify which envelope was opened first, and hence the draw of the participant for that period.
- The participant then opens the second envelope to verify that it held the other type of calendar/draw.

While we do not anticipate having randomization errors, should they occur, we will drop those participants from the study.

Each participant will be enrolled for 6 2-week periods. In addition, they will respond to an eligibility survey roughly 2-4 weeks prior to enrollment and complete a follow-up survey 1 month following the end of the active study period.

All participants will be enrolled from a single site surrounding Tamale, Ghana.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

The study was designed to allow us to both: 1) identify the effect of income instability on mental health. For this, it is crucial to hold average income constant when varying income instability. And 2) decompose the effects of predictable and unpredictable instability and compare them to the effect of increasing the level of income, we will compare the outcomes in the predictable and unpredictable arms to the stable income and control arms. Additionally, we will isolate the effect of *ex-ante* income uncertainty by comparing participants who have *ex-post* identical income realizations. Each of these analyses are explained in greater detail below.

Effect of Level. We will estimate this effect by comparing the Control and Stable Income arms. The study earnings of both of these arms will be stable over time.

Effect of Predictable Instability. We will estimate this effect by comparing the Stable Income and Predictable Instability arms. While the two arms will earn on average the same, the earnings of the Predictable Instability arm will vary over time while those of the Stable Income arm will not.

Effect of Unpredictable Instability. We will estimate this effect by comparing the Predictable Instability and Unpredictable Instability arms. While the Predictable Instability arm has a known average, the Unpredictable Instability arm will earn the same amount *in expectation*. The difference between them is that a Predictable Instability participant can anticipate the swings in her future income while the incomes of Unpredictable Instability participants are unpredictable. As discussed before, this difference between the two arms has two consequences. One is the *ex-ante* income uncertainty, i.e., the Predictable Instability participant knows what to expect while the Unpredictable Instability does not. The other is that an Unpredictable Instability participant may have an income realization which is different from what she initially expected.

We explain next how our design permits separately estimating these two distinct consequences of unpredictable instability.

Effect of Ex-Ante Income Uncertainty. We will estimate *ex-ante* income uncertainty by comparing Unpredictable Instability and Predictable Instability participants with *identical earnings profiles over time*. E.g., we will compare the Unpredictable Instability participants to the Predictable Instability participants. They had identical profiles over the first 4 periods. But, the Predictable Instability participant knew these income swings in advance while the Unpredictable Instability participant did not. The comparison is internally valid because the earnings profile for the Unpredictable Instability participant is randomly determined. To compensate for using a subsample of the arm, more individuals will be assigned to it.

Effect of Income Realizations. We will estimate the effect of income realizations (what actually happened) by comparing Unpredictable Instability participants who by chance end up with different income realizations.

Table 4: Group Comparisons and the Effects They Estimate

Comparison of	*Estimates Effect of*
Stable Income to Control	Level of Income
Predictable Instability to Stable Income	Predictable Instability
Unpredictable Instability to Predictable Instability	Unpredictable Instability
Unpredictable Instability and Predictable Instability with Identical Earnings Profiles over Time	*Ex-Ante* Income Uncertainty
Unpredictable Instability w/ Diff. Income Realizations	*Ex-Post* Income Realizations

Justification of the Control: For our study we will randomly select individuals from those determined to be eligible to serve as an internal control group for comparison as there may be significant time trends in this population given the progression through the lean season. These individuals will be surveyed following the same timeline as all other participants, but not participate in the work program. Given that our sample density is less than five percent in any selected village, we do not anticipate spillovers from randomly sampled individuals in treatment arms to or from individuals in the control arm.

4.3 JUSTIFICATION FOR INTERVENTION

In order to ensure the needed variation, it is important that participants engage heavily with the work offered and that those offered less work do not compensate heavily outside the study. To ensure this is the case, we will conduct the study in the lean-season leading into the harvest, when cash is very much needed (consumption often dips heavily during this time) and work availability is quite low (typically just a few days per month). While we are relatively confident that limited work is available outside of the study given previous research in this area, we have planned for a year of piloting to allow us to evaluate whether the work provided is sufficiently attractive to ensure high and consistent engagement with the work offered.

4.4 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if he or she has completed the baseline assessment and the endline assessment.

The end of the study is defined as completion of the 1-month follow-up assessment shown in the Schedule of Activities (SoA), **Section 1.3**.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

The study will take place in communities/districts around Tamale in the Northern Region of Ghana. The randomization will be conducted to ensure that there will only be one participant per household. Households will be randomly selected to partake in a screening survey in 135 villages to identify eligible participants. Individuals will be eligible if and only if:

1) They are between the ages of 18 and 65. Only individuals of legal age to work will be enrolled to ensure compliance with local laws. Further, restricting the sample to adults (18 and over) ensures all participants are able to provide informed consent and are in compliance with local labor regulations. Enrollment is limited to those under 65 given that the nature of the work may be physically taxing and generate additional risk for these individuals.
2) The participant is female. This restriction is needed for two reasons. First, the study requires high take-up of the work offered in order to provide interpretable results and women are less likely to have other work obligations that would generate partial participation. Second, gender norms in the area make the work provided (sewing) relevant to women but not men.
3) To guarantee that the data collection is feasible within short time windows, large households, with many working adults, will not be eligible to participate in the study. The exact limit of this cutoff will be determined using pilot data.
4) All participants must provide informed consent.

5.2 EXCLUSION CRITERIA

We will exclude women who are pregnant as pregnancy and the post-partum period are often associated with depression unrelated to one's work environment (and hence less likely to be impacted by our treatments). However, no participants will be dropped from the study if they become pregnant during their participation and wish to continue.

5.3 LIFESTYLE CONSIDERATIONS

N/A

5.4 SCREEN FAILURES

Screen failures are defined as participants who do not meet the inclusion and exclusion criteria defined above or those who decline to participate after completing the informed consent procedure. These individuals will be thanked for their time, but will have no further contact with the study. They will not be rescreened at a later date as all study enrollment happens in a limited time window driven by the study design.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

We expect to screen roughly 10,000 households to reach our enrollment target of 2,267 participants. Households to be screened will be determined by a random sampling procedure within the targeted villages until the target number of households is reached. The target number of households per village will be a function of the village size, to ensure a relatively sparse randomization. These interviews will be conducted in person as in-person data collection will result in more accurate screening data and avoid any concerns around unreliable cell service and limited literacy. All of these households will be located in the vicinity of Tamale, Ghana. Local enumerators who are fluent in the local dialects and familiar with these areas will be enlisted to undertake this screening. Enumerators will not work after dark for their safety in traveling. To ensure participant safety, the interview will take place in a location of the participant's choice near or in their home and the study team will conduct back-checks and flag any discrepancies from protocols for review with a supervisor.

The screening will produce a household roster to identity potentially eligible individuals within the household. Consistent with the inclusion and exclusion criteria of the study, these individuals will be non-pregnant women between 18-65 years old living in (relatively) small households.

This process will result in roughly 2,267 African women between the ages of 18-65 being enrolled into the study (see inclusion/exclusion criteria for justifications for age restrictions).

The household screening survey used to determine eligibility will be conducted over the course of approximately 4-5 weeks in the spring of 2025. We will then enroll all participants in the study in 2-4 weeks in late March to early May of 2025. The pilot study will be conducted in the late spring/early summer of 2024.

The study will include multiple survey rounds. Participants will be provided with incentives (cash or in-kind gifts, to be determined via piloting) for their participation in the surveys. This compensation is intended to be similar to or slightly above (25%) compensation for their time in the local labor market. In addition, this data collection will be made as convenient as possible via collection by phone or in which the surveyor travels to meet the participant at their house. To date, our implementation partners (IPA Ghana) have had excellent retention in studies in this area, often exceeding 90%. All survey payments will be made directly to the respondent.

Importantly, participants in the treatment groups are also compensated for their time working as a part of the study. The compensation is roughly 25-50% above the local minimum wage, an amount which we believe compensates them sufficiently for their time while not providing undo inducement. Payments for work will be made three times throughout each two-week period as the work is completed.

Because participants are economically disadvantaged and some may not literate, we will ensure comprehension of the informed consent by reading all documents to the potential participant and will ensure comprehension of the key points via comprehension questions and checks.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

The poor are known to suffer disproportionally from poor mental and physical health. Many causes for these disparities have been considered, including low income. Yet, poor families' incomes are not only low, but also often unstable and unpredictable (Collins et al. 2009). Income instability creates uncertainty about whether they will be able to safeguard their future wellbeing: Will they have enough money to put food on the table? To pay for rent? To pay for a doctor's visit? (Jolliffe and Ziliak 2008; Bhattacharya et al. 2004) The allostatic load framework posits that, if uncertainty (of any type) is not resolved, prolonged activation of physiological stress responses will cause "wear and tear" on the body, heightening risks of cardiovascular disease and of age-related metabolic diseases, promoting cognitive decline and dementia, and accelerating cellular aging (Peters et al. 2017). Income instability could therefore increase the rate of aging among the poor and contribute to disparities in physical and psychological health.

In order to parse the impacts of volatility and uncertainty on mental health, we must vary both the variance in income and what is know about the expected path of income among participants while holding constant the mean expected income.

To accomplish this, all participants are enrolled in the study for 6 two-week "periods" (3 months) and a short follow-up survey one month after the end of the active study period. During the study period participants are randomly divided into the following four groups.

1) *The Control Arm*. The Control arm will not be hired by the cash-for-work program but will be surveyed.

2) *The Stable Income Arm*. The Stable Income arm will work the same number of hours (36) and earn the same amount (108 GHS) every period.

3) *The Predictable Instability Arm*. The hours and earnings of the Predictable Instability arm will vary over time. In three periods, the participant will work longer hours (60) and will earn more (180 GHS). In the remaining three periods, she will work fewer hours (12) and will earn less (36 GHS). Crucially, she will be able to predict all swings in her study earnings in the future—i.e., she will know her hours and earnings in each future period.

4) *The Unpredictable Instability Arm*. The hours and earnings of the Unpredictable Instability arm will vary unpredictably over time. In any given period, there will be a 50% chance that she works longer hours (60) and earns more (180 GHS) and a 50% chance that she works fewer hours (12) and earns less (36 GHS).

Common to all treated arms: Importantly, participants are not required to complete all of the work that they are offered. As a result, Predictable Volatility and Unpredictable Instability participants will have the option to implement, if they wish, a fixed work schedule with non-varying earnings. If in periods when offered 60 hours, the participant voluntarily chooses to work just 12 hours, she can ensure to always work 12 hours and always be paid GHS 36 (per period). Similarly, any other number of days within the maximum number of days offered is also allowed without penalty. All wages will be paid daily for work that is completed. As such, there is no penalty for non-attendance at any level.

We believe the effects of income volatility and uncertainty on mental health are likely to operate through economic channels. Hence, the study will collect data on key economic indicators such as household consumption, savings, and debt.

The targeted clinical endpoints are as noted in Section 3.

6.1.2 ADMINISTRATION AND/OR DOSING

The study operates in 6 2-week "periods." Within each period, treated participants are provided with materials to complete their work in the first few days of the period. They then follow a schedule of collections and payments over the next ten days. Finally, in the final 4 days of the period, all participants including the control, complete their survey. A dedicated staff will provide the materials, collect the completed work, and make payments for the completed work. These staff are hired via PAS, a local NGO which has engaged in a similar intervention in the past. A separate staff will conduct surveys. These staff are hired via IPA Ghana, a non-profit research organization with extensive experience in conducting surveys in the field and by phone.

The participants will compete the work (i.e. the intervention) in their homes. The intervention is considered "full dose" if the individual completes at least some work in each period. As participants are paid for each unit of work completed, we are able to track the "dosage" for each individual in great detail.

The work from home design and sparse randomization (roughly 1% of the village population) is intended to minimize participant interactions, though participants are in no way prevented from interacting with each other as they usually might in the village.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

It is important to have consistent administration of the study interventions. To ensure this is the case, we have:

1) Found an implementation partner with previous experience in very similar work in a previous academic study
2) Generate the work plans using a fixed set of schedules that are easy to follow and can be monitored via the data on material drop-off and pick-up/payments. This will allow us to quickly catch and address any deviations from the intended plan. This data is updated daily at the end of the day and code is run to flag any deviations. Supervisors then check in with their supervisees about these deviations and make a plan to correct any deviations. Additionally, study participants have access to a "hotline" to report any concerns about deviations from expected schedules or protocols.
3) Planned for a pilot to ensure that operations are running smoothly prior to launching the study at scale.

We do not anticipate any variability in delivery, with the exception of random shocks (e.g. heavy rainfall that delays the delivery of materials) which will likely impact all arms equally. We have

generated contingency plans to mitigate the effects of such shocks (e.g. each participant is given additional material at the beginning of the study to be used in such cases).

Changes in the structure of the experimental arms over the study will be tracked via two data sources:

1) Data on the completion of the offered work, as described above
2) Data on the completion of the bi-weekly surveys.

Given the high retention of participants of studies with similar interventions in this region with our implementing partner, we expect that retention in the study will be over 90% in all arms. Should retention be significantly lower than expected or imbalanced across study arms, we should identify this concern in the pilot and will be able to adjust protocols (e.g. to increase convenience), compensation, or timelines (i.e how close to harvest the study is conducted) to address these concerns.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

We will recruit 2,267 participants, randomly assigning 400 to the Control, 400 to the Stable Income, 400 to the Predictable Volatility, and 1,067 to the Unpredictable Instability arm. Among those in the Unpredictable Instability arm, we expect 1/3 to end the study with the same average earnings as those in the Stable or Predictable volatility arm. Roughly 1/3 will earn more overall and roughly 1/3 will earn less overall, given the randomized draws. Participants are not (and cannot be) blind to their condition. The randomization will be conducted using Stata or R following the completion of the screening process. Because not all individuals selected via screening will consent, we will identify "backup" participants in each wave of enrollment to reach our target enrollments. We will stratify the randomization within village to improve power.

2,267 Participants			
400 Control	400 Stable Income	400 Predictable Volatility	1,067 Unpredictable Instability

The period-by-period randomization for the amount of work received by each participant in the Unpredictable Instability arm will follow the protocol described in Section 4.1.

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

The participant's adherence to study procedures among treated participants will be tracked using the same datasets used to track fidelity to the intervention because this dataset captures not only that the material was provided to the participant, but also what work the participant has completed using that material. This dataset, generated from the electronic surveying records, allows us to track that engagement with the work provided is high and consistent across all arms of the study. Data is uploaded and a monitoring script is run daily.

However, participants will be retained in the study (and all corresponding survey activities) regardless of their engagement with the work provided as long as they wish to do so.

Adherence to surveys will also be tracked via the electronic surveying software used. We will generate bi-weekly reports (the same frequency as the surveying) on survey engagement across study arms.

We will work to survey all participants originally recruited, including any who drop out of the program, and expect a high tracking rate because: (i) the endline will be conducted only three months post-baseline; (ii) we will stay in frequent contact through the phone surveys; and (iii) IPA Ghana has a strong follow-up protocol and rates (over 94% (Amadu et al. 2018; Wolf et al. 2018)). We will estimate bounds if response rates vary across arms. Given IPAs performance on previous lean season surveys (when respondents typically have time), we anticipate 5% attrition across all arms.

6.5 CONCOMITANT THERAPY

N/A

6.5.1 RESCUE THERAPY

No rescue medications will be used. However, appropriate referral procedures are in place to provide counseling and support to those experiencing extreme mental distress. See section 8.2 for additional details.

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

No interim analysis is planned because the study is minimal risk (i.e. participants are always able to opt out of the work offered, neither the work nor the surveys are riskier than everyday activities). Given this, there are no study stopping rules for the study as a whole. Similarly, there are no criteria for individual discontinuation, should the individual wish to continue.

However, we do anticipate that individuals may need to discontinue participation at times and may wish to restart later. For example, the study takes place in an area with high disease burden. Hence, an individual who falls ill with a fever may wish to stop participation for a few weeks to recover and then rejoin.

We do not anticipate any SAE, AE, or UP in the administration of the study given that the work (sewing bags) is low-risk and the surveys are no more than minimal risk. Further, because the income generated by the study can be very valuable, both in material and psychological terms, we do not plan to involuntarily remove anyone from the study as the result of an adverse event unless they would like to discontinue. Should an individual wish to discontinue, we would collect any remaining sewing, make the corresponding payments, and thank the participant for their participation. If the individual wishes to restart at a later date (while the study was still ongoing),

they would be allowed to do so and would simply rejoin as soon as logistically possible (typically within one week).

Should an unanticipated AEs or SEA arise that was determined to be study related (to be determined by the site investigator and the PI following the procedures in the data safety and monitoring plan), this would be reported to the relevant IRB within 48 hours and to the DSMB members at the next DSMB meeting. For AEs and SEAs related to health, participants will be referred to the closest government health post or hospital, depending on the severity of the event. The costs of transportation for AEs and SEAs considered related or potentially related to study participation will be covered by the study.

If they so wish, their participation in the study would be halted until they felt able and willing to rejoin.

Regardless of whether a participant discontinues engagement with the intervention, they will be asked if they are able and willing to continue with the ongoing surveys. These surveys are an important component of our participant safety protocols as they allow us to screen and refer participants with significant signs of psychological distress (see Section 8.2). Should a participant not be available at their home for the in-person survey, we will attempt to contact them to complete a shortened version of the study instrument via phone. Notably, we collect multiple forms of contact information at enrollment to allow us to track participants who have changed their phone numbers.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participation may be discontinued at the participant's request for voluntary withdrawal from the study. The reason for discontinuation will be recorded in the participant's tracking form. The PI will not discontinue any participants for non-compliance, but if a participant is deceased, they will be removed from the study. Additionally, the study will continue to try and contact a participant if they have not explicitly asked us to discontinue such contact, though this contact may be shifted to telephonic communication if the participant has relocated a significant distance from their original home. Participants who discontinue their participation or remain unreachable will not be replaced. However, subjects who sign the informed consent form and are randomized but do not receive their treatment assignment information or study intervention may be replaced. Power calculations have accounted for potential loss to follow up.

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if he or she fails to complete the endline survey or at least 3 of the phone surveys. If a participant is unavailable or not present at their home at the time of the endline survey, 2 additional attempts will be made to contact the individual and schedule a new time for the survey. If they are unable to complete the survey in person at their home, we will ask if they are willing to take a shortened form of the survey by telephone.

All phone-based surveys must be conducted prior to the beginning of the following period. Hence, if the participant remains unreachable after 4 call attempts during this window, no further attempts will be made to recontact them for that survey round. However, the standard protocol will be followed at the next round of data collection in two weeks.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Endpoints

Surveys will be conducted at baseline and every two weeks throughout the study as well as once roughly one month following the study. The baseline and "endline" (following period 6) are conducted in-person and are longer, typically taking about 2.5 hours. All other surveys are conducted by phone, typically taking under 30 minutes. These surveys will be used to collect our primary and secondary outcomes, described in section 3 as well as measures of channels (primarily economic outcomes), and demographics. These outcomes include:

Mental Health Outcomes:

- Anxiety
  - Abbreviated Version of General Anxiety Disorder (GAD-2)
  - General Anxiety Disorder-7 (GAD-7)
- Depression
  - Abbreviated Version of Patient Health Questionnaire (PHQ-2)
  - Patient Health Questionnaire-8 (PHQ-8)
- Stress
  - Abbreviated Version of Cohen's Perceived Stress Scale (PSS-4)
  - Cohen's Perceived Stress Scale (PSS)
  - Cortisol (Participants will be asked to provide a small sample of hair to measure cortisol levels. There is no penalty for declining this request. The hair collected will be from the approximately 2 cm below the cranial bone and cutting off 2-3 strands of hair, following the hair collection study protocol developed by the Biomarker Network. The hair samples will be collected at the participant's home and analyzed in a single laboratory.)
- Wellbeing
  - Diener's Satisfaction with Life Scale
- Worry
  - Penn State Worry Questionnaire (PSWQ)

To ensure that the measures are well-understood, the translations will be validated, by a local mental health expert, Dr. Ben Weobong of the University of Ghana. Further, to ensure consistency in the translation and understanding, the survey items will be pre-recorded and played via the tablet used to conduct the survey. The enumerator will then simply key in the response provided

by the participant. Scoring of the scales above follows the standardized approaches/scoring of these measures which are all common in the existing mental health literature.

Physical health related outcomes:

- Blood pressure
- Weight
- Dietary diversity and sufficiency

Enumerators will receive extensive training in the collection of blood pressure and weight measures.

Measures of channels, such as:

- Consumption
- Labor supplied outside of the study
- Gifts/transfers
- Debts/savings
- Assets/wealth

Demographics (abbreviated list):

- Age
- Size of household
- Education
- Marital status

Screening process
The study will take place in communities/districts around Tamale in the Northern Region of Ghana. Surveys will be conducted in 135 villages to identify eligible participants. Local enumerators who are fluent in the local dialects and familiar with these areas will be enlisted to undertake this screening. These individuals are not doctors and do not have any medical training, but none of the screening criteria are medical in nature.

The screening will produce a household roster to identity potentially eligible individuals within the household. Consistent with the inclusion and exclusion criteria of the study, these individuals will be non-pregnant women between 18-65 years old living in (relatively) small households.

This process will result in roughly 2,267 African women between the ages of 18-65 being enrolled into the study (see inclusion/exclusion criteria for justifications for age restrictions).

The household surveys used to determine eligibility will be conducted over the course of approximately 4-5 weeks in the spring of 2025. We will then enroll all participants in the study in 2-4 weeks in late March to early May of 2025. Pilot participants will be enrolled in late April and May of 2024.

Additional details
As the study is not clinical in nature, no clinical care will be provided.

8.2 SAFETY ASSESSMENTS

Participant mental health referrals

We will use the mental health data collected via study outcomes to monitor participant safety. Any individuals scoring at or above the thresholds for depression recommended by Dr. Lund (6 on the PHQ-2 scale), individuals whose scores have increased beyond a threshold of more than two since baseline, or those expressing suicidal ideation, will be contacted by phone within two days and asked if they would like to avail themselves of telephone-based counseling via a local NGO providing mental health services. Given the potential for stigma around mental health concerns in the local context, this option will be presented "as a person to talk with about any concerns that are on your mind." Counseling is phone-based to improve access as many individuals cannot travel for in-person counseling. The counseling sessions will be without charge to the participant whether or not a participant decides to continue study enrollment and regardless of study arm. Our aim is to support participants in their decision of whether to participate or not, and they should not feel concerned that their study participation is jeopardized by reporting poor mental health or other crises.

Further, in rare cases when a participant indicates thoughts of suicide, self-harm, or harm to others, Mind 'N' Health has an action protocol to, first, collect relevant details on the situation for assessment and, then, initiate follow-up actions with Ghana Health Services including in-person services at local government-run health facilities. With the participant's consent, Mind 'N' Health will also work with the individual's family to facilitate access to these additional services. We will also send a study team member in person to visit any participant expressing suicidal ideation who is not able to be reached by phone within 48 hours. This study team member will offer the counseling services in person and help the individual place the call if they are interested in accessing services.

The NGO providing the counseling is well established in the area. The minimum qualification of providers is a first degree BSc. in mental health nursing. Providers include psychologists, psychology therapists, certified counselors, and guidance and counseling experts. Services are available in all local languages that participants are expected to speak.

No results of the cortisol assays will be provided as the assays will be conducted some time after the completion of the study and the results are not clinically actionable.

Adverse event identification

Given the high disease burden in Ghana, it is anticipated that some participants are likely to become ill with diseases endemic to the area (e.g., malaria, coughs) but unrelated to their participation in the study during their enrollment in the study. We also anticipate that a large number of both treated and control participants will experience depression and anxiety during their participation due to their challenging economic circumstances. It is also likely that some workplace injuries (e.g. repetitive motion injuries) occur given the nature of the work and the large number of participants. The rate of these injuries per day is expected to be comparable or lower for treated participants given that the work provided is less physically taxing than work

typically found in the area. However, overall rates may be higher given the additional work provided.

Given that we do not anticipate any adverse events associated with participation, we do not aim to gather systematic data to track such events. However, two reporting options are available to participants: 1) a study "hotline" to call regarding any concerns about their participation in the study, and 2) an open-ended question on each survey administered about any concerns about their participation. Any potential AEs or SEAs reported through these channels will be conveyed from the survey staff to their managers and from the managers to the PI and site-investigator.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS

Adverse Event (AE): Any untoward or unfavorable medical occurrence in a human study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

Serious Adverse Event (SAE): Any adverse event that:

- Results in death
- Is life threatening, or places the participant at immediate risk of death from the event as it occurred
- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity
- Results in congenital anomalies or birth defects
- Is another condition which investigators judge to represent significant hazards

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

Mild: Awareness of signs or symptoms, but easily tolerated and are of minor irritant type causing no loss of time from normal activities. Symptoms do not require therapy or a medical evaluation; signs and symptoms are transient.

Moderate: Events introduce a low level of inconvenience or concern to the participant and may interfere with daily activities, but are usually improved by simple therapeutic measures; moderate experiences may cause some interference with functioning

Severe: Events interrupt the participant's normal daily activities and generally require systemic drug therapy or other treatment; they are usually incapacitating

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

Definitely Related: The adverse event is clearly related to the investigational agent/procedure – i.e. an event that follows a reasonable temporal sequence from administration of the study intervention, follows a known or expected response pattern to the suspected intervention, that is confirmed by improvement on stopping and reappearance of the event on repeated exposure and that could not be reasonably explained by the known characteristics of the subject's clinical state.

Possibly Related: An adverse event that follows a reasonable temporal sequence from administration of the study intervention, follows a known or expected response pattern to the suspected intervention, but a number of other factors could readily have produced that.

Not Related: The adverse event is clearly not related to the investigational agent/procedure - i.e. another cause of the event is most plausible; and/or a clinically plausible temporal sequence is inconsistent with the onset of the event; and the study intervention and/or a causal relationship is considered biologically implausible.

8.3.3.3 EXPECTEDNESS

Unexpected - nature or severity of the event is not consistent with information about the condition under study or intervention in the protocol, consent form, product brochure, or investigator brochure.

Expected - event is known to be associated with the intervention or condition under study.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits or via the hotline described above. If this occurs, they will be captured on a case report form which includes the time, a description of the event or concern, and current status of the participant.

Any AEs or SAEs that are deemed unrelated to the study will not be followed up. Any AEs or SAEs deemed potentially related to the study or definitely related to the study will be tracked and monitored every two weeks throughout the study until resolved.

8.3.5 ADVERSE EVENT REPORTING

All definitely or possibly related AEs will be immediately reported to the Principal Investigator, and then he/she will immediately inform the Institutional Review Board overseeing this project. In addition, the Principal Investigator will provide an annual summary report of all adverse events to the IRB as part of the annual review and to the Federal Agency as part of the annual Progress Report. If no adverse events have occurred, the report will state, "No adverse events affecting human subjects have occurred during this project year."

In addition to the above, please note that per NIA policy, all adverse events, regardless of their seriousness, severity or relatedness to the intervention, are reportable to the NIA PO and an independent data and safety monitoring body such as a Data and Safety Monitoring Board (DSMB) or a Safety Officer (SO), if one is appointed by NIA. Semi-annual reports (for adverse events) will be reported to NIA PO.

Note that we anticipate a large number of disease-related events given the study population. These disease-related events include diseases endemic to the area (e.g. malaria, GI distress, fevers, injuries). We do not explicitly collect data on these medical concerns as they are unrelated to the goals or likely consequences of the study and hence will only report on them as brought to our attention by study participants.

We also anticipate poor mental health (e.g. high levels of depression and anxiety from baseline onward on screening surveys). These conditions are also not considered adverse events as no diagnostic activities are completed within the study, and will not be reported in this reporting process. However, mental health outcomes will be tracked and referred to counseling, following the procedures outlined above. Suicidal thoughts reported to surveyors will be tracked and reported as an adverse event.

8.3.6 SERIOUS ADVERSE EVENT REPORTING

A summary of all SAEs will be reported to the NIA Program Officer quarterly during all times when participants are enrolled, unless otherwise requested. Additionally, SAEs will be reported to the DSMB at all meetings which follow active periods of participant enrollment.

8.3.7 REPORTING EVENTS TO PARTICIPANTS

N/A

8.3.8 EVENTS OF SPECIAL INTEREST

N/A

8.3.9 REPORTING OF PREGNANCY

The study will not enroll pregnant women as pregnancy related and post-partum depression are common and unrelated to study participation. However, should a women become pregnant

during the trial, she will not be excluded as these concerns are less prevalent early in the pregnancy. Hence, pregnancy will not be tracked or reported.

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

An Unanticipated Problem (UP) is defined as any incident, experience, or outcome that meets all of the following criteria:

- Unexpected, in terms of nature, severity, or frequency, given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the study population;
- Related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research);
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4.2 UNANTICIPATED PROBLEMS REPORTING

Unanticipated problems will immediately be reported to the IRB. The Principal Investigator will consult with the IRB to determine if it is necessary to suspend data collection for modification of the protocol or other changes. Other changes will include a corrective plan and measures to prevent reoccurrence. Resumption shall be based on the concurrence of the Principal Investigator, the IRB and any other relevant parties. We will report such events within 48 hours to the NIA unless they are also SAEs. We will also report unanticipated problems, as defined above, to OHRP using ohrp@osophs.dhhs.gov within two weeks of the event.

Note: Per NIA policy, all deaths require expedited reporting (usually within 24 hours of study's knowledge of death). The report of death should be submitted to the NIA Program Officer. When SAEs occur that are unanticipated (i.e., not listed in the Data and Safety Monitoring Plan) and that are related to the intervention, they should be reported to the NIA Program Officer within 48 hours of study's knowledge of SAE.

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

N/A

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

We hypothesize that the impact of the treatments on our primary endpoints will be positive overall (due to the increased work and income), but that the Stable Income will have the largest treatment effects, the Predictable Volatility arm the next largest, and the Unpredictable Instability arm the least (though still positive relative to the control). Alternatively, our null hypothesis is that there will be no difference among the experimental arms.

9.2 SAMPLE SIZE DETERMINATION

Given IPAs' performance on similar previous surveys during the lean season (when respondents are relatively available), we assume a uniform 5% attrition across all arms.

We will recruit 2,267 participants. 1,067 will be assigned to the Unpredictable Instability arm and 400 to each one of the other three study arms. About 37.5% of the Unpredictable Instability arm (i.e., 400 individuals) are expected to have Neutral 4-period schedules, such that the estimation of the effect of ex-ante income uncertainty corresponds to a randomized controlled trial with a sample size of 760 (95% of 800) equally split between "treatment" and "control". For a two-tailed test with 0.05 significance level and 0.8 power, the minimum detectable effect (MDE) is 0.2 of a standard deviation (SD) for each primary outcome (calculations done in Stata). These effect sizes are consistent with those found in the literature on the effects of cash transfers in low-income settings (e.g., Haushofer & Shapiro, 2016 & 2018; McIntosh & Zeitlin, 2020). Similarly, the MDE for the effect of predictable income volatility is also 0.2 SD. The estimation of the effect of income risk, which corresponds to RCT where 72.7% of the 1,394 (95% of 1,467) participants are assigned to the treatment condition, has an MDE of 0.17 SD. The estimation of the effect of income realizations has an MDE of 0.19 SD if those with unlucky and lucky schedules are grouped together and of 0.23 SD if they are each compared separately to those with Neutral schedules. For panel data analyses, standard errors will be clustered at the individual level (the unit of randomization) (Abadie et al. 2017). These are conservative estimates that consider data from the follow-up survey only; they ignore that we will have baseline measures of all outcomes of interest, which should substantially reduce MDEs, and that we will have repeated measures of most outcomes. In addition to an index of mental health, given the rapid evolution of multiple hypothesis testing techniques, will we use state of the art techniques to adjust for multiple hypothesis testing.

9.3 POPULATIONS FOR ANALYSES

The primary analysis will be intention-to-treat (all randomized participants).

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

To study the effects of uncertainty, we will compare the outcomes of participants assigned to the Unpredictable Instability arm to the outcomes of participants assigned to the Predictable Instability arm, while holding the payment schedule constant. Similarly, to study the effects of predictable income volatility, we will compare the outcomes of participants assigned to the Predictable Instability arm to the outcomes of participants assigned to the Stable Income arm. Finally, we will estimate the effects of a stable income by comparing the outcomes of participants assigned to the Stable Income arm to the outcomes of participants assigned to the Control arm.

For each of the individual outcomes, the primary regression model will be:

$$Y_{it} = \lambda_0 + \sum_{\{k=1\}}^{3} \lambda_1^k T_i^k + \boldsymbol{\lambda_2 X_i} + \lambda_3 Y_{i0} + \gamma_t + \epsilon_{it}.$$

where i indexes the individual; Y_i is individual i's outcome in the post-treatment period t; T_i^k is an indicator for treatment arm k; $\boldsymbol{X_i}$ is a vector of individual-level controls (e.g., age); Y_{i0} is the dependent variable at baseline; and; ϵ_i is the error term. Period fixed effects (γ_t) are also included to control for period effects. The analysis considers treatment assignment as the independent variable, regardless of compliance (i.e., intent-to-treat). We utilize an ANCOVA regression model. Standard errors are clustered by individual. $\boldsymbol{\lambda_1}$ are the key coefficients of interest and can be interpreted as the causal effect of each treatment relative to the control group. Additional comparisons between treatments will be conducted to parse the impacts of predictable and unpredictable volatility. Also, to study if outcomes fluctuate together with income, we will compare participants from a given arm with different current study earnings (but who had identical earnings in the past). Given the rapid evolution of multiple hypothesis testing techniques, will we use state of the art techniques to adjust for multiple hypothesis testing.

A pre-analysis plan will be registered after the pilot but prior to the main study with any updates to this analysis plan based on learnings from the pilot.

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

We will use the standardized scoring approaches to all mental health outcomes, including any reversals of scale items as needed. These measures are repeated as described in the timelines previously.

ANCOVA regressions, as outlined in section 9.4.1 above, will be run to analyze the differences between experimental arms. Standard errors will be clustered by individual in all panel regressions. Results will be presented in a regression table with point estimates and standard errors. The regressions will be intention to treat (ITT) with all available data. Data will be cleaned to winsorize outliers, but no imputation will be conducted. If attrition is imbalanced, bounding exercises will be conducted. Given the rapid evolution of multiple hypothesis testing techniques, will we use state of the art techniques to adjust for multiple hypothesis testing.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

Secondary endpoints are not dependent on primary outcomes but rely on standardized scales for mental health measures. Weight will be measured in kilograms. We will examine both absolute

changes in the weight level as well as percentage changes in weight. Economic measures will generally be measured in local currency to allow for standardization. Secondary measures are also generally repeated, with the exception of weight which is only captured at baseline and endlineThe same regression approach will be used for secondary outcomes as described above for primary outcomes.

9.4.4 SAFETY ANALYSES

N/A

9.4.5 BASELINE DESCRIPTIVE STATISTICS

A baseline balance table comparing demographics (e.g. age, assets), baseline measures of primary outcomes, and baseline measures of economic covariates will be generated prior to the analysis. The table will include means and standard deviations by group as well as p-values for tests of equality between each treatment arm and the control.

9.4.6 PLANNED INTERIM ANALYSES

N/A

9.4.7 SUB-GROUP ANALYSES

While there are reasons to expect that the effects of income instability may vary with age, we are not aware of any prior evidence that strongly suggests the effects may vary by race or ethnicity. Nonetheless, because these effects are of interest, we will augment our primary regression specification – detailed above – to study heterogeneous treatment effects along a number of key dimensions. This analysis will include the covariate of interest (main effect) and its interaction with each of the treatment dummies (interaction effects) to assess which individuals are affected the most by income instability. This is a standard and unbiased statistical analysis to compare whether covariates of interest modify the effects of income instability. This assessment will include baseline covariates likely to moderate the impact of the instability (including age, baseline levels of psychological health and of assets). Given the racial homogeneity of the anticipated study population, no heterogeneity analysis is planned for racial differences at this time.

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

Data will be collected by both individual and timepoint. The final dataset that is released will be structured as a panel with the individual-period as the row and the covariates and outcomes as columns.

9.4.9 EXPLORATORY ANALYSES

Exploratory analyses will be noted in the pre-analysis plan developed after the pilot.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

All households screened for participation provide verbal consent for the screening.

Participants considering enrollment in the RCT will complete a more detail informed consent procedure. Consent forms describing in detail the study intervention, study procedures, and risks will be given to the participant and written documentation of informed consent will be completed prior to starting the study intervention. All consent materials will be read to the study participant, given that literacy cannot be assumed in the study population. Participants will sign or fingerprint the consent form to indicate their agreement to participate. The following consent materials are submitted with this protocol:

- Informed consent – Information sheet, to be given to participant
- Statement of consent, to be signed and kept on file

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

We will conduct a household survey following a random sampling procedure in each village to identify eligible individuals. If eligible and interested, the prospective participant completes the informed consent procedure, which includes the following information:

- Participants are free to exit the study at any time without repercussions and no event would preclude participants from continuing their participation if they desire to do so.
- Participants can choose not to answer questions asked by the surveyor
- Random assignment to study conditions
- Study activities, duration, weekly time commitment, and compensation
- Confidentiality, risks, and benefits from participating

The surveyor will read the informed consent document to the prospective participant, ask comprehension questions, explain or clarify any points of misunderstanding, and ask the individual if she would like to participate in the study. The document is read to the prospective participants given the low literacy levels of many in this setting. Participants will be asked to consent with a signature or fingerprint for those who cannot sign their name. The consent document will be written in the local language and all consent procedures, surveys, and activities

will be conducted by surveyors fluent in that language. To ensure that the translation of the consent forms, surveys, and other study materials is accurate, once the study documents are translated, a local Research Associate will check the accuracy of the translation of all documents one by one by back-translating the documents (without having seen the original) and then discussing and resolving any points of confusion. All study staff will have completed a Human Subjects training and have certificates documenting this process. The surveyors will also be thoroughly trained in survey and activity administration. Finally, all participants will be provided with the phone number to a study hotline that they can call or text if they have questions.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the funding agency and regulatory authorities. If the study is prematurely terminated or suspended, study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance of study staff to the protocol (i.e., significant protocol violations)
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, IRB, and DSMB.

10.1.3 CONFIDENTIALITY AND PRIVACY

Protection of Subject Privacy
All in-person surveys will be administered in or near the participants' home. The surveyors are trained to seek out a location that provides the most privacy possible for the respondent. For example, they may suggest sitting in the shade of a nearby tree rather than in the house. However, the final location of the survey is left to the participant to decide as they are most able to judge what makes them comfortable. Additionally, phone-based surveys will be designed to minimize the amount of information disclosed (e.g. asking a participant to respond with the number of the appropriate option or point to a visual scale rather than the answer itself for sensitive questions).

Data Management and Security
Beyond the steps taken to protect participant privacy in collecting the data, a large number of steps are taken to maintain the confidentiality of the data once collected. For example, all data is stored under a participant study ID rather than the individual's name. Further, the data is stored on an encrypted server or laptop and only the Research Associates and site investigator will have the password used to decrypt the data or link the data to the participant's name.

Enumerators and their supervisors have access to contact information during the study administration so they can locate participants. At the interviews, the participant's information will be cross-checked with the original roster data and the data will be entered using the

participant's unique identifier. All the data will be labeled with the unique identifiers. Identifying information will be removed from the data set and stored in a separate file to be destroyed at the conclusion of the study and NIH mandated storage period. Survey personnel will receive training in protecting respondent confidentiality.

Consent regarding privacy
In order to enroll, participants will listen to a summary of the data storage and sharing policies in the study, and orally consent to those policies as a part of the informed consent procedure. Personally identifying information (PII) will be separated from all remaining data during the study. Following NIH policy, PII will be destroyed within three years of the conclusion of the study unless the participants request we keep their name and contact information on file for future studies.

Future use and release of data
De-identified data will enter the public domain after publication, given protocols which require this at many academic journals. No individually identifiable information will be shared or disseminated, including to the DSMB. At DSMB meetings, data and discussion are confidential. While aggregate statistics and reporting on individual SEAs will be undertaken, participant identities will not be known to the DSMB members.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

The cortisol levels will not be assayed until after the study is complete given the relatively short nature of the study. However, the specimens will not be retained beyond their use in the study. As such, there is no additional information provided to the participants about these samples in the informed consent beyond the fact that we will request and analyze them.

10.1.5 KEY ROLES AND STUDY GOVERNANCE

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The study will also rely on a Data Safety Monitoring Board, as described in the Data Safety and Monitoring plan. Study team roles are described in the manual of procedures.

10.1.6 SAFETY OVERSIGHT

Safety oversight will be under the direction of a Data and Safety Monitoring Board (DSMB) composed of individuals with the appropriate expertise, including mental health in low-income settings, econometrics/statistical methods, and the administration of large field-based RCTs. These members are:

1) Dr. Johannes Haushofer (National University of Singapore and Stockholm University): Dr. Haushofer holds a BA in Psychology, Physiology and Philosophy from Oxford, a PhD in Neurobiology from Harvard, and a PhD in Economics from Zurich. Prior to his current role as Professor of Economics at Stockholm University and Goh Keng Swee Professor of Economics at the National University of Singapore, he was an Assistant Professor of Psychology at Princeton. He has conducted numerous RCTs on mental health in low-income settings and has extensive experience in measuring key outcomes such as depression, stress, and anxiety in these settings. In addition, his second PhD in economics makes him well-placed to understand the empirical methods which will be used.

2) Dr. Jacob Bor (Boston University): Assistant Professor and Peter T. Paul Career Development Professor in the Departments of Global Health (primary) and Epidemiology. His research applies the analytical tools of economics to the study of population health, including the estimation of spillover effects of healthcare treatments and causal inference in public health research. His role on the DSMB would be to bring his methodological expertise to the complex analysis involved in this study.

3) Dr. Ingunn Marie Engebretsen: Pr. Engebretsen holds a Ph.D form the Faculty of Medicine, University of Bergen, Norway. She is a Professor at the Centre for International Health and is leading the Global Mental Health Research Group at the University of Bergen. She is active in global health research with a particular focus on mental health and child health (nutrition, growth and child mental health). Her main methodological focus has been quantitative research involving trials, surveys and cohorts, but also qualitative research including interviews, observations and focus-group discussions, and in addition mixed methods. Pr. Engebretsen has worked on large trials as a member of the PROMISE consortium and other experimental designs. She brings to the DSMB her expertise in research on global mental health and in supervising clinical trials in low-income countries.

The DSMB will operate under the rules of an approved charter that will be reviewed at the first DSMB meeting and approved by the members prior to the start of the trial. The DSMB will provide its input to appropriate individuals at the NIA.

Data Safety and Monitoring Board – Meeting timelines

The initial DSMB meeting will begin prior to the 400-participant pilot scheduled for May of 2024. Following that meeting, the NIH default meeting schedule for a DSMB is every 6 months. However, this study recruits participants very rapidly and those participants are then only enrolled for 3 (active) months and a one-month follow-up. After this period, there is a pause on study activities where no further participants are enrolled for eight months. Then, the process

resumes. Given this timeline, the default meeting timelines every six months are ill-suited for this study.

Here instead we will plan to meet with the DSMB after sufficient data has been collected within a wave to ensure issues are identified as they arise. This allows for more timely feedback from the DSMB and, also, reduces the number of meetings with the DSMB in which no new information is available to be presented. In other words, we will arrange for the DSMB to meet once per year roughly 4 periods into the study (typically in June) during the active phase and will present information on the safety and efficacy of each arm at that time.

10.1.7 CLINICAL MONITORING

N/A

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

Quality control (QC) procedures will be implemented as follows:

Informed consent – Study staff will review both the documentation of the consenting process as well as a percentage of the completed consent documents. This review will evaluate compliance with GCP, accuracy, and completeness. Feedback will be provided to the study team to ensure proper consenting procedures are followed**.**

Survey fidelity – Electronic surveying will be used to improve survey fidelity. For example, this method allow us to validate data in real-time via checks on appropriate values and ranges, provide consistent administration of mental health measures through pre-recorded audio, and monitor surveyor time and location to identify outliers and allow supervisors to determine the cause of such outliers.

Intervention Fidelity — Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study. Procedures for ensuring fidelity of intervention delivery are described in Section 6.2.1, Interventionist Training and Tracking.

Protocol Deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

High Frequency Checks (HFCs), Back Checks (BCs), and Spot Checks will be designed by IPA project staff to monitor and measure quality of the data collected by enumerators. These checks will help detect survey related issues such as questionnaire programming errors, data fabrication, surveyor errors and poorly understood questions among others.

Daily HFCs will be conducted on incoming data to flag potential survey and response errors for prompt correction and reconciliation. Checks for survey coding inconsistencies, missing data, outliers, too many similar responses, duplicates in respondent IDs, survey progress and surveyor performances will be implemented on incoming data using Stata commands and SurveyCTO built in features.

During data collection in the first week, all enumerators will be accompanied by their team leaders or supervisors to provide the necessary support to ensure the collection of high-quality data. Spotchecks by the team leader or field supervisor will also be done. In the case of accompaniment, a team leader or field supervisor will visit enumerators while an interview is ongoing to monitor the line of questioning, understanding of questions, observance of survey protocols and the overall conduct of surveyors in an uninterrupted manner and feedbacks provided to enumerators for improvement. For spot-checks, team leaders or field supervisors will pay an unannounced visit to enumerators to ascertain that the survey is ongoing, at the right place and at the right time.

In addition, back-checks (BCs) will be conducted on already interviewed respondents using some selected questions from the questionnaire. BCs will be administered by an “auditor”, who will be different to the surveyor that administered the original survey to the specific respondent. This will help to check the consistency of the responses by participants. The standard practice at IPA is that at least 10% of all surveys for all surveyors must be back checked in the first week of survey launch. The responses from the back checks are compared to the original questionnaire responses to see if there are any discrepancies. The aim is to check for the accuracy of responses, the robustness of the instrument, the performance of surveyors and the potential falsification of data by them. In the case where discrepancies are detected, further probing will be conducted to know the sources of those discrepancies and actions taken to reconcile them.

Data security measures are described in Section 10.1.3.

10.1.9.2 STUDY RECORDS RETENTION

The NIH requires that the records be retained for three years following the completion of the study. This study will comply with that policy. After that time identifiers will be destroyed and only de-identified data will be retained and made available.

10.1.10 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

It will be the responsibility of the site investigator to use continuous vigilance to identify and report deviations within 7 working days of identification of the protocol deviation, or within 7 working days of the scheduled protocol-required activity. All deviations will be recorded in study source documents. Protocol deviations which are more substantial in nature will be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator and PI will be responsible for knowing and adhering to the reviewing IRB requirements.

10.1.11 PUBLICATION AND DATA SHARING POLICY

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, the full RCT will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. We will submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

Further, we recognize that the dissemination of the research results plays an important role in the advancement of knowledge and research in the field, and are therefore committed to sharing the final research data and analytical codes used to process and analyze the data. We are also aware that the rights and privacy of people who participate in the research must be protected at all times.

All final data and code will be posted to institutional website(s) by the end of the project. We will post relevant data and code with corresponding working papers as they are released. The project will ensure any datasets resulting from the research and made publicly available will be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of individual subjects.

We will publish the results of our work. Papers will primarily be published in peer-reviewed journals. Relevant data and code will also be posted to the website of any journal that publishes any papers resulting from this project, provided that the journal's website allows for this.

Our findings will also be disseminated via direct contact with government bodies and NGOs, as well as the media and presentations at policy and academic conferences. These outreach efforts will be made with the support of our local partner, IPA, which maintains strong relationships with policymakers and stakeholders at the local and national levels in Ghana. Dr. Schofield will also use her extensive contacts in India, including previous collaborations with state governments and

the policy arms of her lab's partners, to disseminate the results in India as well – a hugely populous country with many similar small-holder farmers facing similar income instability concerns. Finally, we will use Cornell's expertise to disseminate the research results in a wide range of formats useful to broad audiences including blog posts, policy statements, and news articles.

10.1.12 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the NIA has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

Further, all DSMB members will sign a conflict-of-interest statement which includes current affiliations, if any, with pharmaceutical and biotechnology companies (e.g., stockholder, consultant), and any other relationship that could be perceived as a conflict of interest related to the study and / or associated with commercial interests pertinent to study objectives.

10.2 ADDITIONAL CONSIDERATIONS

N/A

10.3 ABBREVIATIONS AND SPECIAL TERMS

The list below includes abbreviations utilized in this template. However, this list should be customized for each protocol (i.e., abbreviations not used should be removed and new abbreviations used should be added to this list). Special terms are those terms used in a specific way in the protocol. For instance, if the protocol has therapist-participants and patient-participants, those terms could be included here for purposes of consistency and specificity.

AE	Adverse Event
ANCOVA	Analysis of Covariance
BCs	Back-checks
DSMB	Data Safety Monitoring Board
HFCs	High-frequency checks
IRB	Institutional Review Board
ITT	Intention-To-Treat
MOP	Manual of Procedures
NIH	National Institutes of Health

PI	Principal Investigator
PAP	Pre-analysis Plan
QA	Quality Assurance
SAE	Serious Adverse Event
UP	Unanticipated Problem

10.4 PROTOCOL AMENDMENT HISTORY

Version	Date	Description of Change	Brief Rationale

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