Creating Access to Resources and Economic Support: A Randomized Controlled Trial of the Efficacy of a Microfinance Intervention with or without Peer Support to Improve Mental Health Among Transgender and Nonbinary Adults

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Abstract

Background: Transgender and gender nonbinary (TNB) people experience economic and psychosocial inequities that make them particularly vulnerable to financial and mental health harms exacerbated by the COVID-19 pandemic. Sustainable, multilevel interventions are needed to address these harms. The onset of the COVID-19 pandemic galvanized many TNB-led organizations to provide emergency financial and peer support for TNB people negatively impacted by the pandemic. However, the efficacy of these interventions has not been evaluated.

Objective: The CARES study seeks to assess the efficacy of feasible, acceptable, community-derived interventions to reduce economic and psychological harms experienced by transgender people in the wake of COVID-19.

Methods: The study aims to (1) compare the efficacy of microgrants with or without peer mentoring to reduce psychological distress and increase COVID-19 prevention behaviors; (2) examine mechanisms by which microgrants with or without peer mentoring may impact psychological distress; and (3) explore participants' intervention experiences and perceived efficacy. We will enroll 360 TNB adults into an embedded, mixed methods, 3-arm, 12-month randomized controlled trial. Participants will be randomized 1:1:1 to the following arms: (a) a single microgrant plus monthly financial literacy education (enhanced usual care); (b) enhanced usual care plus monthly microgrants (extended microgrants); or (c) extended microgrants combined with peer mentoring (peer mentoring). All intervention arms last for 6 months, and participants complete semi-annual, web-based surveys at 0, 6, and 12 months as well as brief process measures at 3 and 6 months. A subset of 36 participants, 12 per arm, will complete longitudinal in-depth interviews at 3 and 9 months.

Results: Full recruitment began on January 8, 2024 and, as of June 25, 2025, 123 participants have enrolled. Recruitment is expected to be completed no later than March 31, 2025; and the final study visit will take place in March 2026.

Conclusions: This national, online study will address multilevel factors – structural and community – driving mental health inequities in TNB communities. Its equitable community-academic partnership will ensure that study findings are actionable and disseminated rapidly. Clinical Trial: This protocol was registered in ClinicalTrials.gov (NCT05971160) on July 24, 2023.

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Abstract

Background: Transgender and gender nonbinary (TNB) people experience economic and psychosocial inequities that make them particularly vulnerable to financial and mental health harms exacerbated by the COVID-19 pandemic. Sustainable, multilevel interventions are needed to address these harms. The onset of the COVID-19 pandemic galvanized many TNB-led organizations to provide emergency financial and peer support for TNB people negatively impacted by the pandemic. However, the efficacy of these interventions has not been evaluated. The CARES study seeks to assess the efficacy of feasible, acceptable, community-derived interventions to reduce economic and psychological harms experienced by transgender people in the wake of COVID-19.

Objective: The study aims to (1) compare the efficacy of microgrants with or without peer mentoring to reduce psychological distress and increase COVID-19 prevention behaviors; (2) examine mechanisms by which microgrants with or without peer mentoring may impact psychological distress; and (3) explore participants' intervention experiences and perceived efficacy.

Methods: We will enroll 360 TNB adults into an embedded, mixed methods, 3-arm, 12-month randomized controlled trial. Participants will be randomized 1:1:1 to the following arms: (a) a single microgrant plus monthly financial literacy education (enhanced usual care); (b) enhanced usual care plus monthly microgrants (extended microgrants); or (c) extended microgrants combined with peer mentoring (peer mentoring). All intervention arms last for 6 months, and participants complete semi-annual, web-based surveys at 0, 6, and 12 months as well as brief process measures at 3 and 6 months. A subset of 36 participants, 12 per arm, will complete longitudinal in-depth interviews at 3 and 9 months.

Results: Full recruitment began on January 8, 2024 and, as of June 25, 2025, 123 participants have enrolled. Recruitment is expected to be completed no later than March 31, 2025; and the final study visit will take place in March 2026.

Conclusion: This national, online study will demonstrate whether an intervention tailored to reduce material hardship and improve peer support among TNB adults will reduce psychological distress. Its equitable, community-academic partnership will ensure rapid dissemination of study findings.

Trial Registration: This protocol was registered in ClinicalTrials.gov (NCT05971160) on July 24, 2023.

Keywords: clinical trial, depression, anxiety, peer support, minority stress, cash transfer

Introduction

Financial and Mental Health Inequities

The COVID-19 pandemic has had devastating impacts on vulnerable communities, including transgender and nonbinary (TNB) people. TNB people are an NIH-designated health disparities population [1] who experience economic and psychosocial disadvantage that make them particularly vulnerable to pandemic-related harms [2]. Baseline data from an observational cohort of more than 1,500 transgender women indicated elevated pre-pandemic levels of poverty (46% v. 11%) food insecurity (48% v. 11%), and survival sex work (21% v 1%) compared with the general U.S. population [2]. Participants also reported high levels of psychological distress (27%), traumatic stress symptoms (41%), and suicidal ideation (28%)–all of which can be exacerbated by pandemic-related stress [2]. Another pre-pandemic study of 850 transgender men also identified high levels of psychological distress (20%), hazardous alcohol use (59%), and polysubstance use (20%) [3]. These pre-pandemic vulnerabilities are consistent with a nationally representative sample of TNB adults in which 48% were living in poverty and 42% had a history of prior suicide attempts [4].

A national poll of 7,000 adults, conducted after the onset of the COVID-19 pandemic, found that twice as many TNB people became unemployed and five times as many TNB people received a pay cut due to the pandemic compared with the general population [5]. A later poll found TNB people were 125% more likely to have reduced work hours since states reopened after COVID-19 lockdowns expired [6]. A longitudinal study of 208 TNB people found significant increases in psychological distress, depression, and anxiety after the pandemic onset compared with prior to the pandemic [7]. A mixed methods study of Latina transgender women found a significant decline in mental health, with the proportion reporting psychological health in the “likely to be well” range falling from 93% (pre-pandemic) to 50% (after pandemic onset) [8]. Qualitative findings indicated that much of this psychological distress was related to pandemic-induced material hardship [8]. In summary, TNB people experienced financial and psychological inequities prior to the pandemic and were highly vulnerable to long-term negative economic and mental health consequences of the COVID-19 pandemic.

Pandemic-induced material hardship has been associated with poor mental health, globally [9]. At the national level, economic recession has been associated with psychological distress [10]. At the neighborhood level, poverty has been associated with depression and anxiety [11]. At the individual level, material hardship (e.g., difficulty paying utility bills, rent, or mortgage, or fear of running out of food) has been associated with poor mental health [12, 13] and worsening of existing mental health conditions [14] independent of other measures of socioeconomic status. Material hardship increases exposure to stressors (e.g., inability to pay for basic needs) and stressful events (e.g., eviction) while also hindering the ability to cope with stress [15, 16]. A recent cross-sectional study of 849 transgender people using structural equation modeling found that socioeconomic loss partially mediated the relationship between pandemic-related societal changes (e.g., social isolation) and poor mental health [17].

Microfinance Interventions

Microgrants (also called cash transfers) provide a small monetary amount to individuals or families, which they do not have to repay. They can be considered structural interventions because they work by altering the economic conditions within which health is produced or reproduced [18]. Cash transfers have been extensively studied in large-scale cluster randomized trials in low- and middle-income countries [19-21] where positive effects on mental health were found [21-24]. A randomized trial with unhoused individuals in Vancouver found that cash transfer recipients accessed stable housing more quickly than controls and increased spending on food, clothing, and rent while reducing spending on alcohol and drugs [25].

Of the two major cash transfer programs in the U.S. – the Alaskan National Petroleum Reserve Impact Grant Program [26] and the North Carolina Eastern Band of Cherokee casino grants [27] – only the Cherokee program has been evaluated. Several studies have demonstrated positive mental health effects of the Cherokee program [27, 28]. While these data provide an important premise for the psychological benefits of cash transfer in the U.S., these programs provide ongoing, long-term, annual revenue generated from business enterprises and do not address whether short-term, targeted microgrants, provided incrementally over several months, can mitigate the long-term negative mental health effects of a pandemic crisis like COVID-19. Data are needed not only to understand if short-term microgrants are effective in improving TNB mental health inequities exacerbated by the pandemic, but also to assess the mechanisms that may account for their effects.

Peer Support Interventions

Social distancing and isolation, key aspects of the COVID-19 pandemic response, have been linked to poor mental health [29]. A longitudinal study of 208 TNB adults found that loss of transgender-specific support during the pandemic was associated with greater intra-pandemic psychological distress [7]. Social support and community connection are known to facilitate mental health recovery after crises [30]. Studies conducted prior to the pandemic indicate that social support via transgender community connectedness can reduce suicidal ideation, anxiety, and depression and buffer the mental health effects of stressors among transgender people [31-34]. These data suggest that supportive transgender community connection (i.e., peer support) may reduce the psychological distress associated with the pandemic.

Peer mentoring is a form of peer support in which a trained peer promotes skills-building with a mentee [35]. Evidence suggests that peer support alone is unlikely to improve mental health in the context of economic challenges [36]. Combining peer mentoring to enhance community connection with microgrants to address material hardship may be more beneficial for mental health than microgrants alone. However, studies of combined financial and peer support interventions are limited, and none have examined psychological outcomes [37-39]. Given the lasting multilevel harms caused by the COVID-19 pandemic and the associated economic downturn, combining an intervention that directly addresses material hardship (structural) with one that provides peer mentoring support (interpersonal) may be most effective.

Community Leadership and Engagement

The COVID-19 pandemic galvanized transgender-led organizations, such as the National Black Trans Advocacy Coalition (BTAC), to provide support for impacted TNB people [40]. BTAC provides peer mentoring as well as referrals and support for health, housing, and employment for TNB people. During the early phase of the COVID-19 pandemic, BTAC provided TNB applicants with a one-time $125 microgrant. They awarded more than 1,200 microgrants and reached more than 5,000 TNB people with health, housing, or employment referrals and/or peer support [40]. However, the efficacy of these community-led social and structural interventions has not been evaluated. Strong community-academic partnerships with organizations like BTAC can ensure that community-derived, relevant, feasible, acceptable, and effective interventions are identified and translated into sustainable change.

Theoretical Framework

The Gender Minority Stress and Resilience (GMSR) model [41] describes the way interventions are expected to act via multiple levels of the National Institute of Minority Health and Health Disparities (NIMHD) Research Framework [42] to mitigate lasting pandemic-induced harms. Briefly, the GMSR model posits that TNB people experience a combination of general (e.g., material hardship) and minority (e.g., stigma) stressors. The excess minority stressors combined with general stressors– experienced regardless of gender identity–lead to mental health inequities. The model posits that

transgender community connectedness will mitigate minority stress and improve mental health. The CARES study (**Figure 1**) will test whether addressing a general structural level stressor (material hardship) alone or in combination with social support (i.e., peer mentoring to increase transgender community connection) at the interpersonal level will improve mental health and COVID-19 risk reduction behaviors without intervening directly on minority stressors [43].

The Creating Access to Resources and Economic Support (CARES) study seeks to assess the efficacy of microgrants with or without peer support to reduce economic and psychological harms experienced by TNB people in the wake of COVID-19. The CARES study builds on TNB community-led interventions, leverages the expertise of an existing TNB Community Advisory Board (CAB), and extends ongoing community-academic partnerships with BTAC. This manuscript outlines the protocol for the CARES Study.

Study Aims and Hypotheses

The CARES Study has three aims and three hypotheses outlined below:

Aim 1. Compare the efficacy of monthly microgrants, with or without peer mentoring, to reduce psychological distress among TNB adults, relative to receipt of a single microgrant.

Hypothesis 1. Receipt of monthly microgrants, with or without peer mentoring, will significantly reduce psychological distress scores compared with receipt of a single microgrant.

> *Exploratory Hypothesis 1.1*: Receipt of monthly microgrants with peer mentoring will significantly reduce psychological distress scores compared with receipt of monthly microgrants without peer mentoring.

Aim 2. Examine mechanisms by which monthly microgrants, with or without peer mentoring, impact psychological distress among TNB adults.

Hypothesis 2. Material hardship will mediate relationships between receipt of monthly microgrants and psychological distress scores.

Hypothesis 3: Transgender community connectedness will mediate relationships between receipt of monthly microgrants with peer mentoring and psychological distress scores.

Aim 3. Qualitatively explore intervention experiences and perceived efficacy with TNB adults.

Methods

Trial Design

This study uses an embedded mixed method design for a three-armed, randomized controlled trial (RCT) with 360 transgender adults. Participants are randomized to one of the following arms: **[A]** the "enhanced usual care arm" which includes monthly financial education videos for 6 months and a single microgrant of $150 at baseline; or **[B]** the "extended microgrant arm" which includes enhanced usual care components with the addition of monthly microgrants of $150 for a total of $900 over the course of 6 months; or **[C]** the "peer mentoring arm" which includes the extended microgrant arm components with the addition of a structured peer mentoring intervention for a total of 6 months. All study procedures are self-administered virtually or interviewer-administered over the telephone as described in the study procedures outlined below (**Figure 2**).

Potential participants complete an interest form that is reviewed by the participant engagement coordinator (PEC) to exclude bots. Once the interest form is reviewed and approved by the PEC, the participant is sent an individualized link to an online pre-screening form. Participants deemed eligible based on the pre-screening form are then scheduled for final eligibility screening by telephone. Eligible individuals take part in informed consent procedures. Individuals who provide informed consent are then stratified by gender identity to ensure balance across gender groups (transgender man, transgender woman, and gender nonbinary) then randomized to one of the 3 study

arms (**Table 1)**. Once the randomized participant completes the baseline survey, they are considered fully enrolled.

Table 1. Overview of Study Arms and Planned Sample Sizes (N=360)

Intervention for Each Study Arm[a]	Peer Mentoring	Monthly Microgrant	Sample Size
A. *Enhanced usual care*: a single $150 microgrant	No	No	120
B. *Extended microgrant*: monthly $150 microgrant x 6 months	No	Yes	120
C. *Peer mentoring*: monthly $150 microgrants x 6 months + peer mentoring	Yes	Yes	120

[a]All study participants will receive brief financial education videos each month for 6 months

Thirty-minute survey questionnaires are conducted at 0, 6, and 12 months. The 6-month survey will assess changes in outcome measures from baseline to the end of the intervention. The 12-month survey will assess for changes in outcomes since the intervention ended. Participants will also complete brief (3-5 minutes) process measures at 3 and 6 months that assess how microgrant funds were spent and participation in peer mentoring sessions and financial education videos. During the course of the intervention, a research assistant (RA) makes monthly outreach calls to confirm identity and contact information for sending microgrants and/or study incentives. A subset of 36 participants will be invited to complete in-depth interviews (IDIs) at mid-intervention (3 months) and post-intervention (9 months) to explore changes in experiences and perceptions during and after the assigned intervention. Participants will be purposively selected for interviews using maximum variation sampling by gender identity, racial identity, and geography.

Ethics Approval

This study has received ethical approval from the Duke University Medical Center Institutional Review Board (IRB; Pro00113319). The Duke single IRB served as the IRB of record for all partner institutions in this collaborative study. Prior to enrollment, all participants complete a detailed consent process, including a consent quiz to ensure understanding of study procedures. All participants electronically sign a written informed consent document. This protocol was registered in ClinicalTrials.gov (NCT05971160) on July 24, 2023.

Eligibility Criteria

Study participants must meet the following self-reported eligibility criteria: (1) age 18 years or older; (2) gender identity different from sex assigned on original birth certificate (inclusive of transgender and nonbinary people); (3) ability to provide informed consent in English; (4) access to a mobile phone and email; (5) a score > 0 on the material hardship index–indicating exposure to at least one material hardship; and (6) willing and able to provide some form of photo identification at enrollment.

Sample Sizes

Quantitative Sample

Statistical power was estimated using the mean and standard deviation from the LITE study, a longitudinal study with 1,273 trans feminine individuals [44]. In this sample, the mean score on the Kessler 6 (K6) measure of psychological distress was 10.67 (SD=5.68). When stratified by food insecurity (a type of material hardship), the difference in mean K6 scores between participants experiencing food insecurity (M=12.14) and participants not experiencing food insecurity (M=9.72) was 20%. Therefore, we considered a 20% or greater improvement in either the extended microgrant or peer mentoring arm compared to enhanced usual care arm at 6 months as a clinically meaningful effect size.

Assuming a baseline mean for the K6 of 12.15 (SD=5.83) for all three groups, no change in the enhanced usual care arm, a 20% improvement over time in either intervention group (Mean=9.72 at 6 months) and alpha of 0.05, power to detect a significant group by time interaction is 0.89 with 110

per group (total N=330), 0.92 with 120 per group (total N=360), and 0.94 with 130 per group (total N=390). Based on the power analysis, we selected a final sample size of 360 with 120 individuals per group. With this sample size, we will retain sufficient power (0.82) even if we observe a 17% difference. We plan to recruit 400 individuals to allow for a 10% attrition rate over the course of the study. However, a sample size as small as 320 (20% attrition) will still provide statistical power that exceeds 80%.

Qualitative Sample

Sample sizes for qualitative research aim to include enough participants to reach the point at which no new, relevant information is gleaned from continued data collection, a concept known as saturation [45]. Studies indicate that saturation often occurs within the first 12 interviews, although early themes can be identified with as few as 6 interviews [46, 47]. To facilitate reaching saturation within each arm, we will conduct in-depth interviews with twelve participants per arm (n=36).

Study Procedures

Recruitment

A growing body of research indicates that digital research studies that recruit through online and social media advertisements are highly susceptible to fraudulent participation by bots and/or enrollment by ineligible participants seeking study compensation [48, 49]. Financial compensation for study participation has been found to increase risk of participant deception about study eligibility [50]. However, failure to compensate participants for the burden of research engagement can be considered unethical [51, 52]. Given that our study intervention includes micrograntpayments, it would be impossible to enroll participants without providing them with money. Therefore, in order to reduce the potential for fraudulent enrollment, the study team has implemented a tailored recruitment strategy as well as several evidence-based screening strategies [49, 53-57] to ensure enrollment only by eligible participants.

The study team leverages community partnerships and existing online observational cohorts of TNB adults for recruitment. BTAC, which is based in Texas and has reached more than 5,000 TNB people with services, has taken a leadership role in recruiting potential participants through their extensive community networks. In addition, the study team has developed a database of numerous transgender-led and/or transgender-focused community organizations across the country whom we are contacting to share information about the study (**Figure 3**). If we are unable to reach recruitment goals through these community-engaged strategies, participants in recent and ongoing TNB-focused studies led by our study team, e.g. the LITE study (N>1,200) and the LEGACY study (N=2,011), who have consented to be contacted for future research will be invited to participate in this study [44, 58].

Screening and Enrollment

Interested potential participants are directed to the CARES study webpage for further information and to complete an interest form. The PEC reviews the email address from the interest forms as well as the encrypted internet protocol address for any indication of fraud, then sends a personalized link to the pre-screener, which ask questions to assess eligibility for the study, as well as collect a phone number, email address, and best times for contact. Participants who prescreen as eligible receive an email informing them that study staff will call or text them to schedule a telephone appointment for enrollment. They are also are offered the opportunity to book a specific time using a calendar link. At the scheduled appointment time, the PEC calls to complete final eligibility screening and conducts the informed consent process. Eligible participants who consent to enroll are randomized to one of the study arms using stratified randomization by gender identity (transgender men, transgender women, and gender nonbinary) to facilitate assessment for gender differences. Once randomized, participants are sent a link to the baseline survey. Participants are considered fully enrolled once the

baseline survey is complete.

Retention

Upon enrollment, participants are asked to provide extensive contact information, including phone numbers, email addresses, and contact person and number in the case study staff are unable to reach them. A dedicated staff member will call participants each month to confirm or update their contact information and will also confirm their identity using date of birth to ensure microgrant payments are being sent to the enrolled individual. The study database has been programmed to automatically send an email and text to each participant when they are due for data collection. Study staff follow-up with telephone calls to participants who do not complete the survey within 10-15 days after the automated message is sent. We have hired study staff from the TNB community to foster cultural competence and optimize acceptability to participants. We anticipate a 90% retention rate over the 12-month study based on our experience retaining 90% of participants over 12 months in the LITE Study.

Quantitative Data Collection

All participants complete a 30-minute self-administered web-based survey at baseline and every 6 months for a total of three full surveys over the course of 12 months. To reduce bias associated with literacy and technology challenges, interviewer-administered surveys will be offered to all participants at enrollment. We have successfully used this approach for our COVID-19 testing study of more than 2,000 TNB adults across the U.S. Study participants will also complete a brief (≤10 minutes) text message survey with only process measures (e.g., number of financial education videos viewed, number of peer mentoring sessions attended, how microgrant funds were spent) at 3 months. These process measures will also be incorporated into the 6-month survey.

A summary of key study measures and their reported internal consistency assessed by Cronbach's alpha, where available, are outlined below (**Table 2**). To facilitate data sharing and population comparisons, primary outcome and potential mediator measures are drawn from the PhenX Toolkit Social Determinants of Health [59] and Mental Health Collections and the NIH Public Health Emergency and Disaster Research Response (DR2) [60]. The primary mental health outcome measure is the K6, a 6-item Likert scale of psychological distress [61]. K6 is a validated, brief, self-report instrument that is low burden for investigators and participants [62]. It can easily be self-administered via the internet and has performed well in prior studies with TNB people [63-65]. The summary scale score ranges from 0 to 24, with scores ≥ 5 consistent with moderate distress [66] and scores ≥ 13 consistent with significant distress [61]. Higher scores on the K6 have been associated with increased risk of all-cause mortality [67]. Reductions in K6 scores have correlated with reduction in symptoms of anxiety and depression [68].

Table 2. Key Study Measures

Construct	Instrument	Variable Type	Source	Cronbach alpha
Mental and Behavioral Health				
Psychological distress	Kessler 6	Primary outcome	Kessler et al. 2002 [69]	0.83 [68]
Substance use disorder	Drug Abuse Screening Test-10	Exploratory outcome	Yudko et al. 2007 [70]	0.94
Economic Hardship				
Material hardship	Material Hardship Index	Potential mediator	Ouellette et al. 2004 [71]	NA[a]
Social Support				
Peer social support	Transgender Community Connectedness	Potential mediator	Testa et al. 2015 [41]	0.90
Discrimination				
Gender-related	Gender Minority Stress and		Testa et al. 2015 [41]	0.90

discrimination	Resilience	Potential confounder		
Intersectional discrimination	Intersectional Discrimination Index-Major	Potential confounder	Scheim et al. 2019 [72]	0.72

[a]NA=not applicable

The primary economic hardship measure is a 7-item material hardship index used in the Coronavirus Impact Survey (CRISIS) V0.2 [73]. This index from the DR2 has been recommended by the U.S. Department of Health and Human Services and included in the federal Survey of Income and Program Participation (SIPP) by the U.S. Census Bureau [71, 74]. The primary social support measure is the validated transgender community connectedness scale, a 5-item subscale of the GMSR measure [41].

While extant data indicate microgrants do not increase substance use [25], we have included the 10-item Drug Abuse Screening Test (DAST-10) as a validated screening tool to assess any changes in substance use over the course of the study [75]. None of the CARES study interventions are hypothesized to affect experiences of discrimination. However, experiences of discrimination (e.g., employment discrimination) may be associated with economic hardship as well as with mental health; therefore, we have included discrimination measures as potential confounders. Gender-related discrimination is a 5-item sub-scale of the GMSR measure [41], included to assess experiences related to TNB identity; and the Intersectional Discrimination Major Discrimination Index (InDI-M) is a 13-item subscale of the Intersectional Discrimination Index [72], included to assess experiences related to any aspect of the participants' identity.

Qualitative Data Collection

Qualitative research is most appropriate for eliciting detailed accounts of participant experiences and perceived efficacy of the interventions. The open-ended nature of IDIs provide the opportunity to more deeply explore issues relevant to the study aims [76]. Prior studies have demonstrated how embedding qualitative data collection within a randomized trial enriches the understanding of how and why the interventions work or do not work [77, 78]. Longitudinal interviews are an important means by which to study how participants experience, interpret, and respond to their assigned intervention over time.

We will conduct one-on-one in-depth interviews (IDIs) at months 3 and 9 to capture intra- and post-intervention experiences and perspectives. Interviews will take place using a HIPAA-compliant video conference platform. Our team has successfully collected qualitative data remotely using this method [79]. We will use stratified sampling [80] to select participants who vary by gender identity within each study arm. We will seek variability by race, age, and geography. Each IDI will last approximately one hour with an interviewer who has been trained in qualitative research methods and has experience conducting research with TNB people.

A topical guide will structure the interview. Open-ended questions, followed by prompts, as needed, will be used to elicit participant narratives. The initial IDIs will begin by exploring the participants' lives, stressors, and coping strategies. The interviewer will then guide the discussion to participants' experiences of the intervention (e.g., how do they spend the microgrant(s), how do they relate with their peer mentor) and how they perceive their financial situation and mental health to have changed or not since the intervention began (i.e., interim perceived efficacy)). Follow-up IDIs will explore how their financial situation and mental health have changed since the intervention ended and discuss their retrospective reflections on the intervention. This qualitative longitudinal design will also enable the study team to clarify in follow-up interviews any unclear or incomplete responses in the prior IDI. All interviews will be digitally audio recorded and transcribed verbatim by a professional transcription company. Interviewers will write field notes and narrative summaries after each interview that will supplement the transcripts. During biweekly meetings, the study team will review field notes, transcripts, and summaries, discuss emerging themes, and revise interviewing and

coding strategies, as appropriate.

Interventions

Comparison Intervention: Enhanced usual care for all study arms

Enhanced usual care interventions include a single microgrant of US$150 provided via virtual or physical Mastercard. In addition, each participant will receive a link to one financial education video, lasting 5-10 minutes, each month for 6 months. Prior research identified financial education as an important need for TNB people [81, 82]. Providing financial education to every participant in all arms will allow the study team to distinguish the effects of financial education (offered to everyone) from the effects of peer mentoring (offered in only one arm). Each video (**Table 3**) is based on content from a financial literacy intervention developed specifically for TNB adults by members of our research team (NCT04275310).

Table 3. Financial Education Video Topics and Knowledge Objectives by Month of Intervention

	Topic	Knowledge Objective
1	Protecting Yourself & Your Money	Identify and avoid predatory loans and financial abuse and coercion
2	Income Generation	Identify job opportunities and considerations for the gig economy
3	Banking	Select and open a bank account
4	Budgeting	Develop a personal budget to meet goals
5	Credit and Loans	Build and maintain good credit
6	Transgender Financial Advisor	Navigate financial systems as a transgender person

Extended Microgrants: Experimental intervention, Arms B and C

Participants in Arms B and C will receive US$150 per month for 6 months, totaling $900, via virtual or physical Mastercard, as outlined for enhanced usual care. During each month of the intervention, participants will receive a phone call from the study team and will be required to respond to verify their date of birth and contact information. After verification, funds will be added to the participants' accounts. Date of birth verification will be the only condition required for subsequent microgrant funds. The study team disburses funds monthly for 6 months in the intervention arms to be consistent with the frequency and duration of interventions in prior research and to align with what would be most sustainable after the study.

In the absence of prior U.S. data on microgrants, the study team explored existing data to determine the amount for each microgrant. The median annual income of LITE participants was less than the federal poverty level at the time (US$12,760 for an individual). Thus, a microgrant of US$150 represents 15% of their monthly income. This is approximately the proportion of income that the average U.S. household spends on food. Since food insecurity is an important element of material hardship, a US$150 microgrant is sufficient to reduce this aspect of material hardship [83].

The research team also considered clinical relevance, ethics, and sustainability. In many U.S. settings, US$150 in a given month may financially support travel expenses (e.g., bus, subway, ride-share, fuel costs) to access employment, mental health, and other social services. The US$150 amount may financially support gender affirming purchases, such as hormones, that can reduce psychological distress [84]. From an ethical standpoint, US$150 was chosen to be substantive enough for economic impact without being so high as to be coercive. Lastly, US$150 was determined by community partners to be sustainable and scalable by community-based organizations in the U.S. as noted by BTAC and demonstrated by the longevity of the Trans Lifeline microgrants program which has distributed > US$1million since 2018 [85].

Peer Mentoring (Experimental intervention, Study Arm C Only)

In addition to the interventions above, participations randomized to Arm C are assigned a peer mentor who matches their gender identity (transgender man, transgender woman, or gender

nonbinary). Gender matching has been found to be an important to rapport-building in mentoring relationships [86, 87]. Peer mentoring interventions are forms of peer support that has been shown to improve mental health [88-90]. Published peer mentoring interventions vary widely in content, structure, duration, and frequency of interactions [35, 91, 92]. A variety of approaches to mentoring can be effective. [93-95], and telephone-delivered peer support is feasible and acceptable [96]. However, while multiple studies have tested transgender peer navigation strategies for engagement in healthcare [97-99], the study team found no published individual (versus group) peer mentoring interventions for mental health with TNB adults. The *Healthy Divas* curriculum (described below) was selected for the CARES study because it was designed specifically for transgender people. It has been successfully implemented and found to be feasible, acceptable, and readily adaptable to diverse settings [100].

The CARES peer mentoring intervention was adapted from the *Heathy Divas* curriculum [101], designed for transgender women, and uses key elements of BTAC's *Akanni* peer support program [102]. *Healthy Divas* is a manualized evidence-informed peer mentoring intervention developed by study consultant Dr. Jae Sevelius, and implemented at HIV care sites across the U.S. [100]. Based on Gender Affirmation [103, 104] and Health Empowerment [105] Frameworks, the intervention improved transgender women's HIV medication adherence through 6 sessions of strengths-based peer mentoring. Guided by the ADAPT-ITT method [106], the CARES team, BTAC leadership, and Dr. Sevelius completed a full-day workshop to adapt *Healthy Divas* for use with TNB people of any gender and HIV status and to focus on participant-selected goal setting. The adapted intervention was manualized by the CARES project coordinator and reviewed by the adaptation workshop participants, as well as TNB community leaders. Revisions were made based on this feedback before pilot-testing with the existing CAB, which has provided our research team with input on TNB-focused studies for several years. After pilot-testing with the CAB, the manual was finalized and used to develop training materials for peer mentors. The final peer mentoring intervention guides the participant in setting achievable goals and building their capacity to reach the goals they have selected. Each peer mentoring session addresses a specific topic (**Figure 4**).

BTAC recruited, interviewed, and hired an experienced full-time peer mentor supervisor as well as three part-time peer mentors. The peer mentor supervisor completed the CARES peer mentoring intervention training and participated in training of peer mentors. In addition to training on the content of the intervention and logistics of implementation, mentor training also included skills-building such as active listening, boundary setting, and self-care [107]. Peer mentors passed the intervention competency assessment, including mock sessions, prior to being matched with Arm C participants. The peer mentor supervisor meets with the peer mentors on a monthly basis for supervision and will make himself available throughout the study period to support the peers. In addition, mentors have access to one-on-one mental health support with a nonbinary professional counselor hired by the CARES study team, as well as vouchers for a limited number of free telehealth psychotherapy sessions. Mentors meet biweekly one-on-one with their assigned participant by telephone or secure video to complete each of the 6 manualized peer mentoring sessions. Peer mentors also meet weekly with the PEC and study coordinator to troubleshoot any logistical issues that arise.

Fidelity to the peer mentorship curriculum is assessed through routine tracking of number, duration, and content of peer interactions by the peer supervisor. In addition, participants in Arm C will complete brief fidelity surveys at 3 and 6 months. All mentors have been provided with a national resource list to link mentees with supportive services as needed. Mentors track all referrals made and assess if the participant utilized the referrals provided.

Data Analysis

Quantitative Data

Quantitative data analyses will be conducted using Stata and/or R. The distribution of all variables will be examined for outliers and to determine if they meet the assumptions of the planned analyses. The pattern of missing data will be explored, including testing for differences on baseline variables between those with and without missing data. Variables related to missingness will be included in the main analyses which should yield valid inferences [108]. In the rare event of more than 10% missing data, we will use multiple imputation. In addition, we will conduct a series of sensitivity analyses to evaluate the robustness of conclusions with respect to departures from missing at random assumption by comparing the magnitude of the primary effect between analysis using complete data only to analyses using multiple imputation. Analysis of variance will be used to test if randomization achieved balance in the baseline participant characteristics across the three arms. Variables on which the groups differ will be included as covariates in the main analyses. We will specify two-sided tests and 0.05 significance level. Below we outline data analysis plans by study aim.

Aim 1: To test efficacy of the interventions (hypothesis 1), generalized estimating equations (GEE) will be used with time (baseline, 6 months), group (A, B, C), and the group by time interaction included in the model. A Gaussian model will be used to examine the K6 Scale. A significant group by time interaction would signify that the change over time differed between the 3 intervention arms. Significant group by time interactions will be graphed and simple main effects will be estimated. In addition, we will examine the maintenance of the effects from 6 to 12 months using linear regression. That outcome will be change in K6 from 6 months to 12 months. Group assignment (A, B, C) will be the main independent variable. Baseline value of the outcome will also be included in the model as a covariate. This will allow us to test if the effect of each intervention is sustained overtime in comparison to enhanced usual care. In exploratory analyses, we will repeat this set of analyses for the DAST-10 to examine if the change over time in substance use differs for the three groups. Exploratory analyses to examine heterogeneity of treatment effects will repeat the above analyses stratified by race, gender, sex-assigned at birth, stigma scores, and other relevant covariates. The effect sizes will be compared across the levels of each strata to determine if intervention effectiveness varies across groups. We will also explore whether efficacy varies by geographic location and compare relative effectiveness of arms (A and B).

Aim 2: We will examine the mechanisms by which the interventions work using structural equation modeling (SEM). Variables in the model will include change from baseline to 6 months in the mediators (Material Hardship Index and Transgender Community Connectedness Scale) and change from baseline to 6 months in the K6 outcome as well as group assignment (**Figure 5**). SEM provides tests of the direct and indirect paths from the independent variable to the dependent variables. Of interest will be the significance tests of the indirect paths from intervention assignment through material hardship to psychological distress (Hypothesis 2) and through community connectedness to psychological distress (Hypothesis 2). We will examine the goodness-of-fit of the overall model (Model Chi-square, Adjusted Goodness of fit, Comparative Fit Index, Standardized Root Mean Square Error of Approximation).

Qualitative Data

Aim 3: Analysts will first compare the transcript to the digital audio recording to identify and correct any transcription errors. Then, transcripts, reflexive notes, and narrative summaries for each interview will be imported into qualitative data analysis software, such as Atlas.ti, to facilitate analysis. Analysis will begin with an open coding phase where data are read iteratively to generate analytic memos and tentative codes [109]. Open coding will be followed by systematic coding by two coders to ensure reliability [110]. To take full advantage of the longitudinal nature of the data, we will apply multiple analytic approaches to the constant comparison technique [111]. We will

review the narrative summaries for each participant over time to look for change within the individual. We will read across the transcripts for each time period to look for themes unique to mid-intervention and post-intervention time periods. Finally, we will read and compare all data across study arms. Analytical memos will be used to track the analytic process and describe themes that emerge. While it is not feasible for coders to be masked to the study arm, initial open coding will take place without attention to intervention assignment. Once coding is complete, we will use advanced visualization features of qualitative data management software to map out any differences in code density by study arm. Findings will be structured to best summarize participants' experiences of material hardship and mental health as well as their perception of their assigned intervention and its efficacy. We will assess variation by race, gender, and geography/cost of living.

Data Integration

Embedding is a type of integration that occurs when different types of data and analyses are linked at multiple points in the study and is particularly useful in intervention trials [112]. In the CARES study, qualitative data will be linked at the randomization phase when participants will be sampled from within each arm after randomization. During the intervention (month 3), qualitative data will facilitate identification of contextual factors that could influence the trial results while also providing detailed information about the nature of the participants' experience by study arm. Qualitative data collected after the intervention (month 9) will facilitate identification of changes that might be necessary for widespread implementation of the intervention. In short, integration will help explain outcomes, improve future iterations of the intervention, and understand mediators and moderators [113]. CARES qualitative and quantitative data will also be integrated at the end of the study using results-based convergent synthesis [114]. This integration method involves analyzing qualitative and quantitative data separately, then merging results during a final synthesis [115]. Results will be merged using joint display [116] in which the interview themes will provide context for the survey results. The qualitative code density (frequency of each code) will be displayed by study arm. Visualization will facilitate identification of similarities and differences in participant experiences across study arms. Process data will be integrated into the joint display to visually assess any relationships between microgrant expenditures (e.g., food, emergency savings fund); dose and content of the intervention (e.g., peer contacts, referrals made and utilized); experience of the intervention (e.g., perceived efficacy); and effect of the intervention on outcomes of interest.

Results

Participant recruitment for the CARES study began as a "soft launch" in November 2023, when we asked our community partners to invite a few participants to screen for the study. Three participants were enrolled during the soft launch phase to ensure that study processes worked as intended prior to opening for full recruitment. Lessons from implementation of this soft launch led to streamlining the enrollment process by implementing a participant self-booking option for scheduling screening and consent appointments. Full recruitment began on January 8, 2024 and, as of June 25, 2025, 123 participants have enrolled. Recruitment is expected to be completed no later than March 31, 2025; and the final study visit will take place in March 2026.

Discussion

Principal Findings

We hypothesize that the CARES study will demonstrate that monthly microgrants, with or without peer mentoring, will reduce psychological distress among TNB adults. Further, we anticipate that reductions in material hardship and an increased sense of connection with the transgender community will mediate these effects. We expect qualitative results to support the perceived

feasibility and benefits of both microgrants and peer mentoring. This study will fill an important gap in the literature, since studies on short-term microgrants in the U.S. are rare [117-119]. We found no prior studies that combine microgrants with peer support, nor aim to use financial interventions to improve the psychological wellbeing of TNB adults [120].

Strengths and Limitations

The CARES study has multiple strengths. Study findings will provide important data on the efficacy of two community-derived, structural and psychosocial interventions to improve mental health among TNB people in the U.S. and potentially mitigate some of the psychosocial harms of the COVID-19 pandemic. The community-academic partnership between BTAC, a national transgender-led organization, and leading research university throughout the research process will ensure that rigorous data will flow directly to the community in real-time. Study findings will provide useful data for BTAC and other community organizations to guide investments of their limited resources toward evidence-based programs. Findings will also have relevance for policy-makers and researchers who seek to address economic vulnerability and mental health among TNB adults.

The CARES study responds to the calls for researchers to address multilevel drivers of health disparities [121] by implementing interventions that operate at the structural (economic) and interpersonal (peer mentoring) levels. Also, this study advances the science behind minority stress theories by testing whether stigma-driven health inequities can be mitigated without intervening specifically on identity-based stigma.

The study has several limitations. While the team has multiple measures in place to prevent fraudulent enrollment, it is possible that people who are not TNB will misrepresent themselves in order to enroll in the study. To reduce this possibility, we are carefully recruiting through transgender-specific organizations, rather than more broadly. There is also the potential for differential attrition in the enhanced usual care arm that my lead to attrition bias. Our staff will conduct monthly check-ins for participants in this arm to enhance retention; and we are closely monitoring attrition by study arm.

Future Directions

The research team plans wide dissemination of study findings across policy (e.g., white papers), academic (e.g. scientific conferences), and community spaces (e.g. town halls) to ensure results have the opportunity to inform future health equity approaches. Ideally, future research will build on this study's findings to develop, refine, and/or test community-derived interventions to enhance TNB wellbeing.

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Data Availability

The datasets generated during the current study will be available from the corresponding author upon reasonable request one year after completion of data collection.

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Conflict of Interest

The authors declare that they have no competing interests.

Authors Contributions

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Funding acquisition: TP
Investigation: AW, SR, LJMW, CB, NP
Methodology: TP, NP, LJMW
Project administration: WK, HK, CB
Resources: TP
Software: AW
Supervision: TP
Writing – original draft: TP
Writing – review & editing: All authors

Abbreviations

BTAC: National Black Trans Advocacy Coalition
CAB: Community Advisory Board
CARES: Creating Access to Resources and Economic Support
CRISIS: Coronavirus Impact Survey
DR2: NIH Public Health Emergency and Disaster Research Response
GMSR: Gender Minority Stress and Resilience
IDI: In-depth interview
IRB: Institutional Review Board
K6: Kessler 6
LITE: Leading Innovation in Trans Equity
NIH: U.S. National Institutes of Health
NIMHD: National Institute of Minority Health and Health Disparities
PEC: Participant Engagement Coordinator
RA: Research Assistant
RCT: Randomized Controlled Trial
SEM: Structural Equation Modeling
TNB: Transgender and Nonbinary

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Supplementary Files

Figures

Theoretical model for the effects of COVID-19 on material hardship and psychological distress among transgender and nonbinary people who experience minority stress.

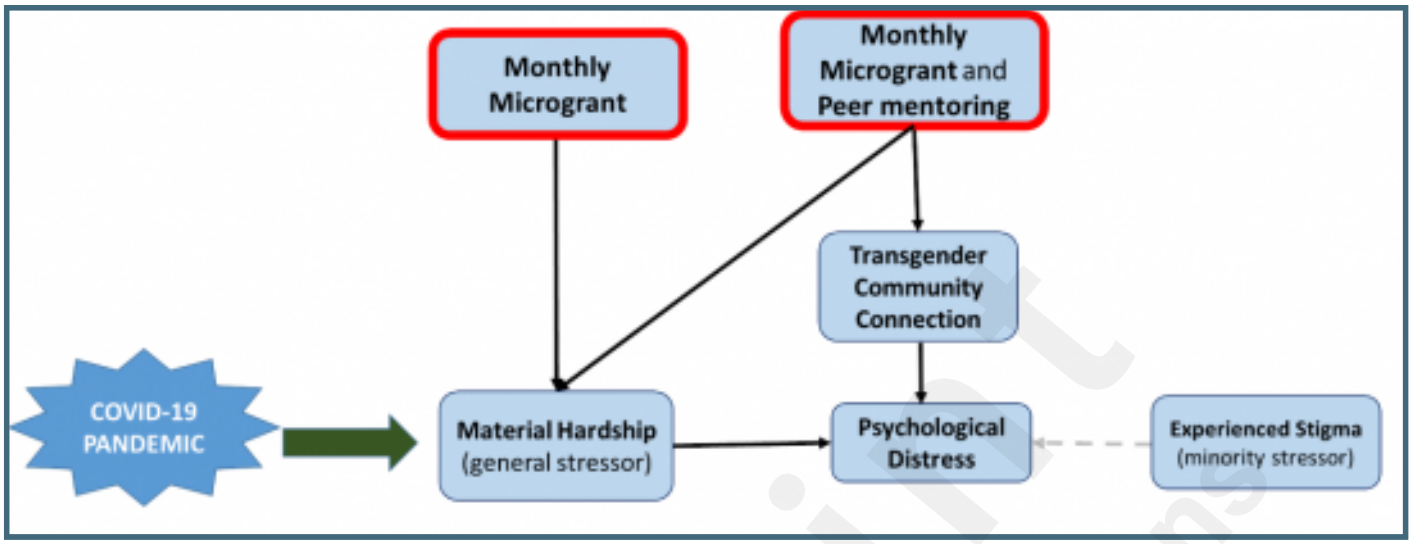
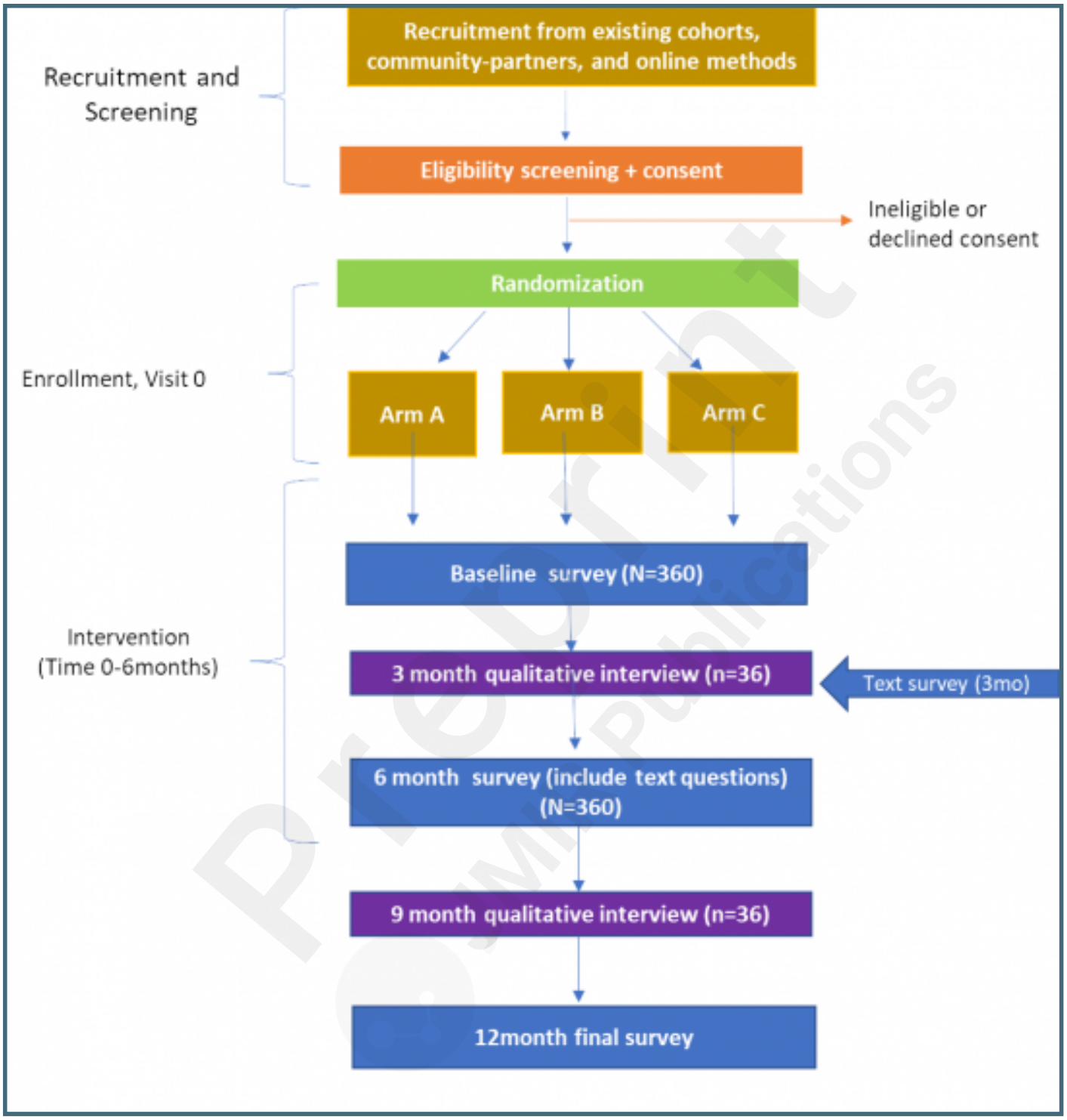
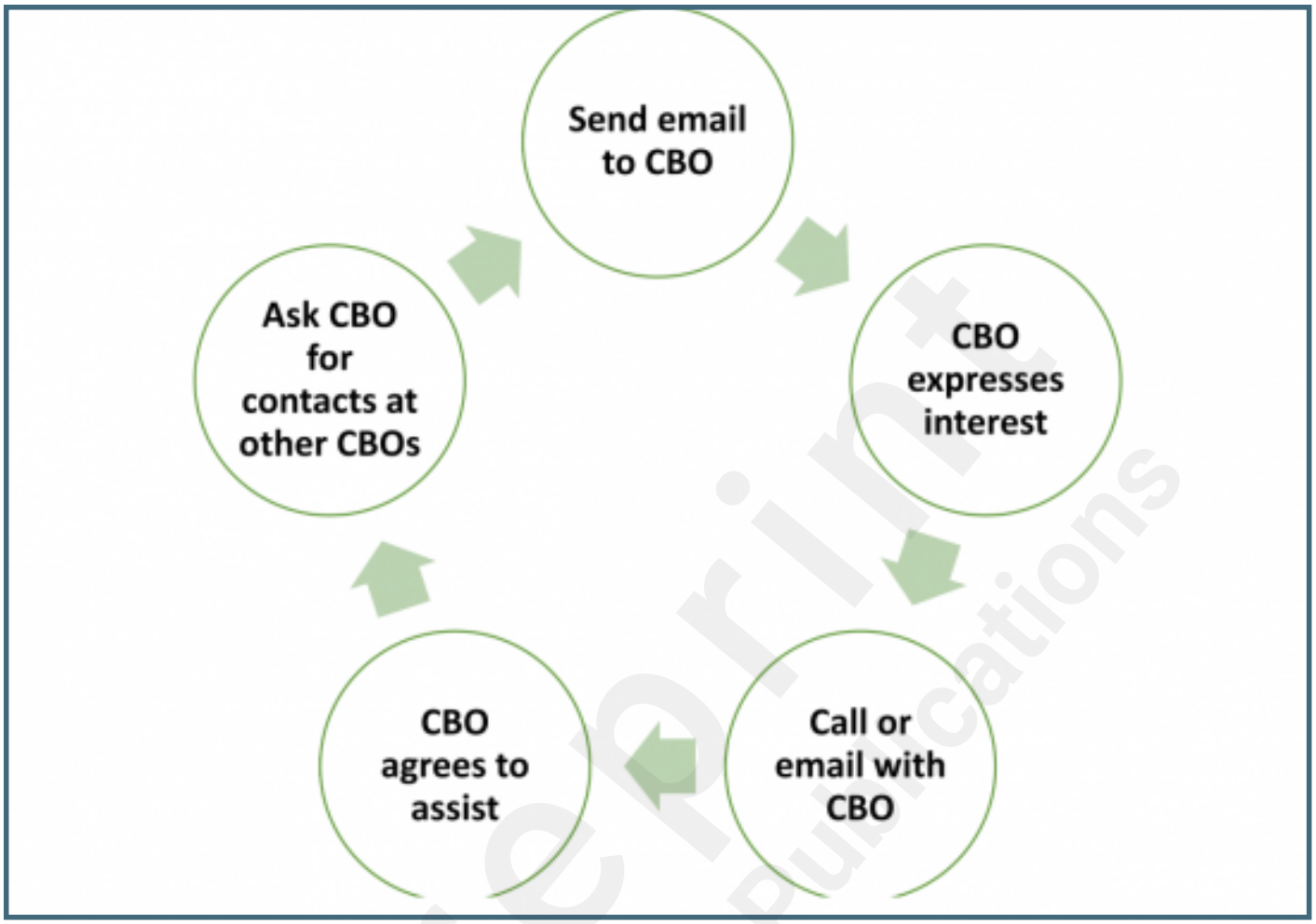


Diagram of CARES Study flow.



Strategy for community-engaged study recruitment with community-based organizations (CBOs).



Content of each CARES Study peer mentoring session.

SESSION 1	SESSION 4
✓ Introductions and expectation-setting ✓ Rapport-building ✓ Identify vision for the future ✓ Level 10 Life exercise ✓ Introduction to goal-setting ✓ Set attainable goals ✓ Amplify gender-affirming experience	✓ Review goals ✓ Review vision for the future ✓ Review kinds of social support ✓ Identify sources of social support ✓ Apply social supports to vision for the future ✓ Set attainable goals ✓ Amplify gender-affirming experience
SESSION 2	**SESSION 5**
✓ Review goals ✓ Identify personal strengths ✓ Connect strengths with goals ✓ Set attainable goals ✓ Amplify gender-affirming experience	✓ Review goals ✓ Review vision for the future ✓ Identify successes ✓ Amplify successes ✓ Problem-solve barriers and challenges ✓ Set attainable goals ✓ Amplify gender-affirming experience
SESSION 3	**SESSION 6**
✓ Review goals ✓ Discuss communication strategies ✓ Practice communication strategies ✓ Set attainable goals ✓ Amplify gender-affirming experience	✓ Review goals ✓ Review vision for the future ✓ Review skills in action from previous sessions ✓ Revisit Level 10 Life exercise ✓ Identify positive vision for the future ✓ Amplify gender-affirming experience

Structural equation model to be tested for Aim 2.

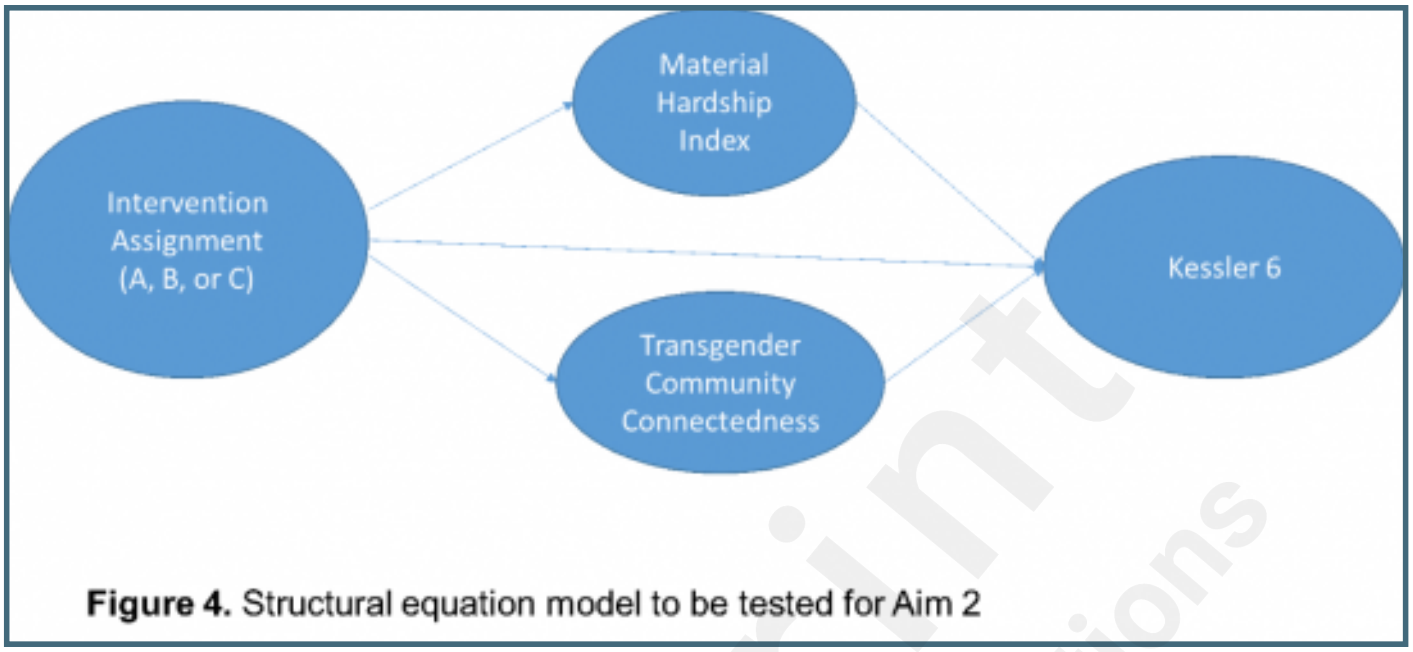


Figure 4. Structural equation model to be tested for Aim 2

Existing Peer-Review Reports from Funding Agencies (for protocols/proposals only)s

Existing Peer Review Reports from NIH.
URL: http://asset.jmir.pub/assets/635f793bc42e105668171cecceece6a4.pdf