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General Study Information

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Study Title: Healthy Immigrant Community

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Research Strategy

1. Significance

By many measures, immigrants arrive in US healthier than the general population.¹ However, the longer they reside in the US, the more they approximate the risk profiles of the general population for cardiovascular disease (CVD) and related chronic conditions (RCC).²⁻⁸ Hispanic and African immigrants experience a racialized environment in the US that differs from their countries of origin.⁹ Repeated experiences of racism, discrimination and marginalization contributes to the chronic stress known to relate to worsening of health status over time and generations in the US.¹⁰ Approximately 15 years after immigration, the prevalence of obesity among immigrants to the US approximates that of US-born adults.⁷ In general populations, dietary behaviors and physical activity are associated with obesity.¹¹⁻¹³ Among immigrant populations to high-income nations, dietary and physical activity behaviors are less healthy than the non-immigrant majority populations.¹⁴⁻¹⁷ Evidence-based health promotion programs in group settings are effective at changing dietary and health behaviors in general populations,¹⁸ but despite calls for interventions to address obesity and obesity-related behaviors among immigrant populations,¹⁹⁻²¹ few treatment studies have been reported.²²⁻²⁴

One difficulty in designing interventions to promote weight loss and healthful behaviors is that the reasons for sub-optimal behaviors among immigrant groups are multiple and complex.^{25,26} Community-based participatory research (CBPR) is a means to collaboratively investigate health topics, whereby community members and academics partner in an equitable relationship through all phases of research and intervention development.²⁷⁻²⁹ This approach is well suited to intervention work that addresses the interplay between health



behaviors and the social determinants of health such that it empowers communities, promotes understanding of culturally pertinent issues, and targets the multi-faceted barriers to health.³⁰⁻³³ Furthermore, CBPR is an effective means of approaching health topics among immigrant populations.³⁴⁻⁴¹ When our partnership began in 2004, there were no published interventions derived in a participatory manner with immigrant communities to address dietary quality, physical activity, or obesity. In addition to our published work⁴²⁻⁴⁸, we are aware of two research teams pursuing similar goals through a CBPR framework, though outcomes are not yet available.^{49 50}

Social networks, social support, and social cohesion, particularly when grounded in activities that enhance cultural values and orientation, are protective against experiences of racism and marginalization that contribute to CVD and RCC.⁵¹ A range of social network characteristics are highly associated with obesity-related behaviors in general populations (nutritional intake and physical activity).⁵² These findings extend to obesity; a 32-year longitudinal study showed that a person's chances of becoming obese increased by 57% if their friends became obese, which was mediated by the frequency and intensity of interactions.⁵³ While there is debate about the possible confounding effects from unmeasured factors and shared environments on the results of this study,^{54,55} sensitivity analyses suggest that contagion effects for obesity are robust⁵⁶, and subsequent work has consistently supported these findings while considering important mediating mechanisms: Structural network factors (e.g., size, density, etc.) may influence obesity-related behaviors through mirroring the behaviors of others,^{57,58} self-comparison⁵⁹ and direct influence of peers to adopt similar behaviors.⁶⁰ Functional network factors may shape obesity-related health behaviors through social norms,^{61,62} social support,^{63,64} and social cohesion,⁶⁵ among other constructs.⁶⁶ In total, while a causal link between social network factors and obesity cannot be demonstrated by a single study, a body of evidence has emerged that strongly supports the contribution of network constructs to the obesity epidemic in the US.⁶⁶⁻⁶⁹

Social network interventions involve purposeful use of existing social networks in the individual's natural environment to promote positive behavior change and health outcomes.⁷⁰ A recent systematic review of network interventions reported consistent findings of positive behavior change with this approach from a variety of settings and across a range of health outcomes.⁷¹ Interventions incorporating social networks for diet and/or weight loss have been identified as a promising and innovative approach,⁶⁸ but few published studies exist. Simulation models suggest that traditional weight loss interventions frequently fail because they lack consideration of the participant's social networks, and that network-driven interventions may be highly effective.⁷² Findings from a randomized trial demonstrated that spouses of partners in a weight loss program may benefit⁷³, suggesting that weight loss interventions may create a contagion effect within social networks. A study incorporating measurement of social networks within weight loss programs have identified that network influences can enhance the uptake of healthful behaviors, but that careful intervention design is needed to avoid propagation of unhealthful obesity-related behaviors.⁷⁴

High quality experimental evidence suggests that higher homophily within social networks -the tendency of social contacts to be similar to one another- significantly improves the adoption of health behavior among obese populations.⁷⁵ Among populations with social disadvantage, homophily may also widen health disparities through diffusion of less healthy behaviors.⁷⁶⁻⁷⁸ Homophily was found to be especially high among social networks of immigrants in Sweden, and immigrants in networks with a high proportion of other immigrants experienced poorer health than those who included a high proportion of natives in their networks.⁷⁹ The authors proposed that network closure (high homophily) may reinforce and maintain norms leading to negative behavior and social conditions in such networks.⁷⁹ These findings are likely to be relevant to escalating obesity rates among immigrant populations in the US with limited English proficiency, who are less likely to use existing evidence-based health promotion programs than general populations.⁸⁰ Therefore, health promotion interventions that use social networks to interface with immigrant communities may benefit from diffusion of positive health behaviors inherent to the programs.

2. Innovation

The proposed study is innovative in several ways: First, the proposed research will be the first to design and evaluate a social network intervention among immigrant populations for health behavior change of relevance to



cardiovascular risk reduction. Through the incorporation of social networks for health promotion, the study team will apply a highly promising intervention approach for curbing the obesity epidemic and associated cardiovascular risk of traditionally difficult to reach populations.

Second, this will be achieved through a trans-disciplinary research team with expertise in CBPR, social network analysis, behavioral psychology, and implementation of evidence-based programs for health promotion. Merging CBPR with social network methodology is innovative, and we will examine the feasibility and acceptability of this promising public health intervention approach.

3. Approach

CBPR partnership experience and narrative

This application builds on our team's experience with CBPR through the Rochester Healthy Community Partnership (RHCP), a 16-year community-academic partnership.⁸¹ RHCP community and academic partners have collectively derived the approach. RHCP has developed an effective community-based research infrastructure that has facilitated extensive research training for community partners.^{82,83} RHCP has become productive and experienced at deploying data-driven programming among immigrant populations.⁸⁴⁻⁸⁷ RHCP first obtained extramural funding in 2008 through the NIH Partners in Research Program to strengthen the CBPR partnership through the development of a culturally sensitive health literacy infrastructure for immigrant populations. In 2011, RHCP received a grant for the Healthy Immigrant Families study described below. In 2018, RHCP received funding for a digital storytelling intervention to improve diabetes self-management behaviors and outcomes among immigrant populations. Community and academic partners jointly conduct every phase of the research and disseminate research results together at community forums and academic meetings as well as co-authorship on scientific publications and presentations.

The study team is uniquely suited to conduct the proposed work. Drs. Wieland and Sia have expertise in designing and implementing health promotion interventions through a CBPR approach.^{44,86} Dr. Valente is an expert in social network interventions.^{88,89} Dr. Patten has expertise in clinical trials of community-based behavioral health interventions.⁹⁰⁻⁹⁴ Dr. Clark has expertise in behavioral weight management.⁹⁵ Dr. Leppin is experienced in implementation and clinical integration of evidence-based health promotion programs, and oversees the WellConnect program.^{96,97} Dr. Herrin has expertise in both cluster randomized studies and in the use of social networks in health research.⁹⁸⁻¹⁰¹ Together with community partners named on this grant (Osman, Goodson, Nur, Porraz Capetillo), this team has worked together closely for up to 15 years.

Specific Aims

Immigrants often arrive to Minnesota with healthier cardiovascular risk profiles than the general population, but these health advantages disappear over time, and rates of obesity quickly increase. Accumulation of cardiovascular risk is precipitated, in part, by systemic factors that promote the adoption of unhealthy behaviors after immigration; namely a sedentary lifestyle and consumption of calorie dense foods. Yet few strategies exist to effectively promote health behavior change in immigrant communities, and clinical health promotion programs are often difficult to access or utilize by patients with limited English proficiency.

Rochester Healthy Community Partnership (RHCP) is a 15-year community-based participatory research (CBPR) partnership in Southeast MN that develops evidence-based health promotion interventions among immigrant groups. In our "Healthy Immigrant Families" project, RHCP partners co-created a face-to-face intervention of 12 modules delivered to Somali and Hispanic participants by bilingual interventionists. At 12 months, there were significant improvements in the primary outcome of dietary quality compared with controls, suggesting this CBPR program could meet the unique needs of immigrant communities. However, the intensity of the intervention limits its dissemination potential, and the intervention did not explicitly address healthy weight loss nor specifically target overweight or obese participants.

RHCP partners then conducted a survey and social network analysis among 1,301 Hispanic (n=610) and Somali (n=691) adults in Rochester, MN and found that obesity clustered by networks and that weight loss intentions were mediated by social norms for obesity, social support, and social cohesion. This prompted the



development of a social network intervention, which have demonstrated efficacy across a range of health and psychosocial outcomes, but none have focused on immigrant communities. Therefore, RHCP partners re-designed the Healthy Immigrant Families intervention materials specifically for overweight and obese adults from Hispanic and Somali communities to be delivered by peer interventionists within their social networks. The resultant group-based social network intervention was pilot tested with 4 groups (2 Somali, 2 Hispanic; total N=39), and despite the onset of coronavirus disease 2019 and a change from in-person to remote groups, the participants demonstrated significant reduction in weight, blood pressure, and cholesterol as well as improvements in their dietary quality and physical activity at 3 months (100% retention rate).

The objective of this work is to leverage existing social networks for health behavior change relevant to obesity and cardiovascular risk among immigrant populations in Southeast MN. In this project our team proposed to build on the prior success of WellConnect, a robust infrastructure developed by a member of our team for implementing multi-level evidence-based health promotion programs and integrating them within health care systems, tailoring these programs to the needs of immigrant communities. To achieve our objective, RHCP partners will test the efficacy of this social network intervention within WellConnect and evaluate its potential dissemination and sustainability as outlined in the following Specific Aims:

Specific Aim #1: Assess the efficacy of a social network-informed CBPR-derived health promotion intervention on obesity and other measures of cardiovascular risk in two immigrant communities.

Hypothesis 1: The intervention will reduce body mass index (BMI) and waist circumference among Somali and Hispanic participants with BMI \geq 25 (goal of 3% weight reduction). Hypothesis 2: The intervention will reduce cardiovascular risk profiles among Somali and Hispanic participants with BMI \geq 25.

Using a stepped wedge cluster randomized design, 60 social network sub-groups of adults (30 Hispanic, 30 Somali) with approximately 480 participants (approximately 7 per group) will be randomly assigned to receive the intervention either immediately or after a delay of one year. The intervention will consist of 12 community-based mentoring and education sessions and group activities, followed by 12 maintenance sessions delivered by trained Somali and Hispanic interventionists to members of their groups in a face-to-face or virtual format. Outcomes measured at baseline, 6 months, 12 months, and 24 months, will be derived from the American Heart Association's "Life's Simple 7": BMI and waist circumference (primary outcomes), blood pressure, fasting blood glucose, total cholesterol, physical activity level, dietary quality, and health-related quality of life. We will also test potential mediators of treatment effect consistent with the C2DREAM conceptual model.

The expected product will be a CBPR-derived, social network-informed intervention to reduce cardiovascular risk among two immigrant groups. The proposed study is innovative; it will be the first to evaluate a social network health promotion intervention among immigrant populations. Given that over one million immigrants arrive in the US annually, the potential public health impact of this work is considerable.

Preliminary Data

Healthy Immigrant Families Study: RHCP partners developed and tested a nutrition and physical activity intervention with immigrant families through a CBPR approach in Rochester, MN.^{42-44,46-48,102} Interventionists from the participating communities (Hispanic, Somali) were trained to deliver the intervention through 12 home visits during the first six months and up to 12 phone calls during the next six months. Forty-four families representing 151 individuals were randomized, and all participating families assigned to the intervention group received 100% of the intervention with very high fidelity.⁴⁴ At 12 months, study retention was high (91% of families, 82% of individuals). For adults, results showed statistically significant improvements in dietary quality compared with controls, with non-significant trends towards improvement in physical activity.⁴² This study demonstrated that implementing a health promotion intervention with high-level contact and intensity, as well as a rigorous, larger scale, randomized controlled trial, is highly feasible in these immigrant communities.

Social Network Analysis: We conducted an analysis of the social networks to identify factors related to healthy behaviors and obesity among 1,301 Somali (n=691) and Hispanic (n=610) participants (50% female) in Rochester, MN. Survey respondents were recruited by bilingual study team members (who were also RHCP



community partners) through multiple approaches, including an RHCP “recruitment to dissemination continuum” that is fueled by past RHCP engagement activities and dissemination events.

Within Hispanic and Somali immigrant populations, overweight and obesity clustered by ascertainable social networks for obesity and obesity-related behaviors. To understand the association between network characteristics and obesity, the following measures were collected from each participant: body mass index (BMI, calculated from weight and height measurements), dietary behaviors, and physical activity level.^{103,104} Participants were also asked about the perceived weight status, dietary quality, and physical activity level for each named alter. 81% of Hispanic and 50% of Somali participants were overweight or obese. Among named alters, 32% of Hispanic and 27% of Somali were perceived to be overweight or obese (discordance with the respondent sample reflects an expected underreporting bias, which skews results towards the null). Despite this underreporting among named alters, we found that for obese respondents, the mean percentage of overweight and obese network members was significantly higher than for healthy weight respondents for the Hispanic network (33.7% vs. 28.7%, $P < 0.001$)¹⁰³, with a non-significant trend noted for the Somali network (14.1% vs. 12.4%).¹⁰⁴ This percentage was also higher for obese respondents than for overweight respondents. There were similar results for obesogenic behaviors, with obese and overweight respondents having a higher proportion of network members with unhealthy diet and low physical activity levels in both networks.^{103,104} These findings confirm that overweight, obesity, and obesogenic behaviors generally cluster according to social networks in these community-based samples of Hispanic and Somali participants.

Among Somali and Hispanic participants who were overweight or obese, the number of social contacts trying to lose weight was associated with weight loss intentions, and this effect was mediated by social norms for obesity, social support, and social cohesion. For obese/overweight participants, we assessed the number of social contacts trying to lose weight, social norms for weight loss, and intention to lose weight in the next three months.^{103,104} Using logistic regression modeling, we found that if most or all of overweight/obese participant’s social contacts were trying to lose weight (29.3% of respondents), the odds of stating they were likely to lose weight was four times higher compared to other participants. In multivariate logistic regression analysis, this effect was mediated by social norms for obesity, social support, and social cohesion.^{103,104} These results indicate that social contacts and normative beliefs influence weight status and intentions for weight control, thereby highlighting the importance of targeting social influence in the treatment and prevention of obesity in these high risk groups.

Healthy Immigrant Community Pilot Study: An RHCP dissemination event was conducted with more than 200 leaders from Hispanic and Somali communities, where preliminary data (above) were presented, and community members were engaged in planning for this pilot. RHCP partners adapted the existing intervention framework that was developed for Hispanic and Somali communities, but changed the content to tailor the intervention to target weight loss among overweight and obese adults; and to provide the flexibility for delivery by community peer interventionists, i.e., Health Promoters (HPs), within their social networks. Twelve modules for healthful eating and physical activity were adapted from existing evidence-based resources¹⁰⁵⁻¹⁰⁷ by working groups of RHCP community and academic partners. The modules were culturally tailored for the audience by changes to approach and content, and incorporated traditional foods in an effort to retain healthy food habits from their original countries while choosing nutritionally sound eating patterns from their new country.¹⁰⁸ An intervention guide was derived for HPs. The intervention consisted of a 12-week behavioral weight loss intervention delivered by HPs (4 weeks in-person, then 8 weeks virtual).

The intervention was tested through a single-arm non-randomized pilot study with 4 social networks of adults (2 Hispanic, 2 Somali; 60.5% female) with 39 participants who were overweight or obese. Feasibility was assessed by recruitment and retention rates. Acceptability was assessed by surveys and focus groups with HPs and participants. Behavioral measures included servings of fruits and vegetables, drinking soda and minutes walking per week. Physiologic measures included weight, blood pressure, glucose, cholesterol, and triglycerides. Retention at post-intervention was 100% (39/39). Participants highly rated the intervention on satisfaction, motivation, and confidence to eat a healthy diet, be physically active, and lose weight (Table 1). Participants were



motivated by group social support and cohesion of their long-standing social networks. On average, participants lost weight, lowered their blood pressure, had more servings of vegetables per day and increased their physical activity (Table 2). All participants completed the program despite the shift in format from in-person to virtual due to the COVID-19 pandemic. The decision was made by each network to continue weekly sessions, where HPs and network members promoted tracking, goal setting, social support, problem solving and motivational strategies. New educational content was not delivered after week 4, supporting the importance of social network factors as a primary mechanism for behavior change in this intervention.

Table 1. Participant Ratings of the Intervention (N=38)

	Percent		Percent
General reaction to the whole program		After completing the program, do you feel confident about eating a healthy diet?	
Really like it	94.7	Yes, much more confident	91.7
Think it was just OK	5.3	Somewhat more confident	8.3
Did not like it	0	No, not at all confident	0
Would you recommend the program to family or friends who are overweight?		After completing the program, do you feel confident about being physically active?	
Yes, definitely	100	Yes, much more confident	91.9
Somewhat	0	Somewhat more confident	5.4
No	0	No, not at all confident	2.7
Did participating in the program make you want to do anything different to be healthy?		After completing the program, do you feel confident about losing weight?	
Yes	94	Yes, much more confident	83.3
No	5.3	Somewhat more confident	16.7
Motivated to exercise	92.1	No more confident	0
Motivated to eat a healthy diet	94.7		
Motivated to lose weight	84.2		

Table 2: Biometric and health behavior measures before and after the intervention (N=39)

	Baseline	Week 12	P value
Weight, kg (SD)	91.6 (15.9)	89.7 (16.6)	< 0.0001
Servings of fruit per day (SD)	1.7 (1.0)	2.9 (2.1)	0.013
Servings of vegetables per day (SD)	1.9 (1.2)	2.6 (1.4)	0.009
Fruits and vegetables as snacks ^a (SD)	2.4 (0.9)	3.0 (0.8)	0.001
Regular soda drinks ^b (SD)	1.6 (0.7)	1.3 (0.4)	0.003
Fruit drinks, punch, or sports drinks ^c (SD)	1.7 (0.8)	1.5 (0.6)	0.10
Total MET-minutes per week ^d (SD)	2689.5 (3230.8)	6595.1 (7371.6)	0.02
Systolic blood pressure, mm Hg (SD)	133.9 (16.9)	127.2 (15.8)	0.001
Diastolic blood pressure, mm Hg (SD)	81.0 (9.5)	75.8 (9.6)	< 0.0001
Waist circumference, cm (SD)	102.3 (13.7)	100.6 (12.3)	0.14
Glucose, mg/dL (SD)	90.4 (18.4)	91.9 (11.1)	0.73
Total Cholesterol, mg/dL (SD)	205.1 (49.4)	190.8 (50.1)	0.02
Triglycerides, mg/dL (SD)	206.1 (175.0)	130.1 (78.6)	0.001

^a4-point Likert scale of frequency in response to, "Do you eat fruits and vegetables as snacks?"

^b4-point Likert scale of frequency in response to, "Do you drink regular soda?"

^c4-point Likert scale of frequency in response to, "Do you drink fruit drinks, punch, or sport drinks?"

^dEnergy expended from carrying out physical activity as measured by the International Physical Activity Questionnaire

Study Design and Procedures

Aim #1: Conduct a randomized trial to assess the efficacy of a social network-informed CBPR-derived health promotion intervention on obesity and other measures of cardiovascular risk in two immigrant communities.

Overview. The first aim address stages II-III of established methods for behavioral intervention research.¹¹⁰ Using a stepped wedge cluster randomized design, 60 social network-based groups (30Hispanic, 30 Somali; each group with approximately 7 participants) will be randomly assigned (stratified by ethnicity, HP sex, and network size) to receive the intervention either immediately (step 1) or after a delay of one year (step 2). Outcomes, measured at baseline, 6 months, 12 months, and 24 months, will be derived from the American Heart



Association's "Life's Simple 7": BMI and waist circumference, blood pressure, fasting blood glucose, total cholesterol, physical activity level, and dietary quality. We will also measure quality of life and potential mediators of treatment effect consistent with our theoretical framework. The intervention will consist of community-based mentoring and education sessions, group activities, and application of a community toolkit for healthy weight loss delivered by trained HPs from Hispanic and Somali communities to their social networks. During the control period, participants will receive printed health information developed by the study team during each assessment that is not directly related to diet or weight loss.

Figure 1. Study Design and Intervention Schedule

Month	0	0	0-5	6	6-11	12	12-18	18-23	24
Intervention Group	Baseline Measures	Randomization	12 peer-led, face-to-face or virtual group-based sessions • Goal setting • Tracking of physical activity and diet • Educational content • Positive reflections	6-Month Measures	12 peer-led, face-to-face or virtual group-based sessions • Goal setting • Tracking of physical activity and diet • Positive reflections	12-Month Measures	Sustainability Phase No Organized Intervention	Sustainability Phase No Organized Intervention	24-Month Measures
Delayed Intervention Control Group			No Intervention		No intervention		12 peer-led, face-to-face or virtual group-based sessions • Goal setting • Tracking of physical activity and diet • Educational content • Positive reflections	12 peer-led, face-to-face or virtual group-based sessions • Goal setting • Tracking of physical activity and diet • Positive reflections	

Blinding. Study staff performing measurements and data analysis as well as all named investigators will be blinded to treatment condition.

Rationale for stepped wedge design. While randomized trials lend maximal validity to study design, the use of control groups in CBPR is problematic in that it may be perceived as withholding of resources that the community helped to create.^{32,111} Therefore, delayed-intervention control groups are frequently used in CBPR contexts.^{112,113} One potential concern with a delayed intervention is differential attrition in control versus intervention arms. However, our prior randomized controlled trial that used the same design found high rates of retention in both study groups over a two-year period (above). In addition, stepped-wedge designs provide increased protection from bias by incorporating both historic and contemporaneous controls, as well as increased statistical power when there is positive within cluster correlation of outcomes over time.^{114 115}

Rationale for social network intervention. In the HIF study, the intervention was delivered to individual Hispanic and Somali families. Participants noted in post-intervention focus groups that a more flexible group-based approach with friends and family may promote greater participation. After reviewing these data in meetings and an RHCP research summit, community and academic partners embraced the conceptual pivot from an intervention delivered among a subset of individuals to an intervention delivered through social networks. Community partners reported this approach as highly acceptable since social network effects are perceived as influential on health behaviors in Hispanic and Somali communities. On the basis of these discussions, the social network analysis conducted by RHCP among 1,301 participants confirmed the influence of obesogenic social network effects in these populations. The subsequent pilot social network intervention was highly successful and enthusiastically received by participants in post-intervention focus groups.

Rationale for addressing obesity. Minnesota Community Health Needs Assessments conducted in 2016 demonstrated that obesity was a priority for intervention. Survey items included in the RHCP social network analysis of 1,301 participants indicated that dietary quality, physical activity, and obesity were among the top health priorities for Hispanic and Somali populations.¹¹⁶ These concerns mirror national trends reflecting increasing obesity and associated co-morbidities among immigrants after arrival to the US.⁷ Finally, 80% of adult participants in the HIF project and 66% of participants in the social network analysis were overweight or obese.¹¹⁷

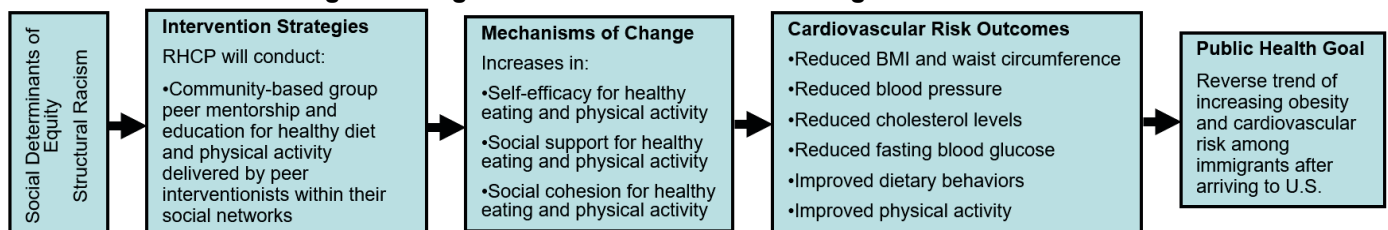


Therefore, RHCP partners concluded that it is appropriate to focus on health behaviors relevant to obesity in the next phase of work.

Rationale for targeting Hispanic and Somali populations. RHCP has a history of successful collaborative work between many different immigrant groups (and non-immigrant Latinos) towards common goals. Our recent RHCP partnership evaluation highlighted the positive impact of this unique collaboration on community building, collective advocacy, and health outcomes. For the Healthy Immigrant Families project and for the social network analysis, community leaders and community-based organizations from Hispanic and Somali populations have taken leadership roles. The work with the two groups has occurred both in parallel and in collaboration, such that best practices and learning opportunities have been shared throughout the process. Furthermore, these represent the two largest immigrant groups to Rochester, MN. If successful, our approach could be used as a model framework for social network level interventions in other diverse populations.

Theoretical approach. This work aligns with the NIMHD research framework and the **C2DREAM conceptual model** by addressing interpersonal and community levels of influence in a sociocultural environment. Social Ecological theory postulates how structural and functional characteristics of social groups (e.g., social networks)^{118,119} influence behaviors through several pathways,⁶⁸ including shared social activities and social support. Social networks can also indirectly influence behaviors in relation to broader conditions for health by addressing modifying and mediating conditions for healthy behaviors.¹²⁰⁻¹²³ Mediating and modifying factors impacting diet and physical activity among Hispanic and Somali immigrants to Southeast Minnesota were elucidated in our formative work, including self-efficacy and social support.^{43,46} Based on our past studies with immigrant communities,^{67,68} we predict that social cohesion will be an important social mediating mechanism for the network intervention. Higher social cohesion, i.e., close relationships among community members with strong mutual trust and reciprocity¹²⁴, has been associated with a range of positive health outcomes.¹²⁵⁻¹²⁷ For the proposed intervention, the empiric relationship between cohesion as a mediator of group (e.g., social network) formation, maintenance, and productivity¹²⁸ is especially relevant. Group cohesion is an established network-level metric¹²⁹ that has been used to assess network intervention implementation progress.^{130,131} Social networks, social support, and social cohesion, particularly when grounded in activities that enhance cultural values and orientation, are protective against experiences of racism and marginalization that contribute to CVD and RCC.⁵¹

Figure 2. Logic Model of Intervention Strategies and Outcomes



Recruitment of peer interventionists. Peer interventionists, i.e., Health Promoters (HPs), will be selected in two ways. First, RHCP community partners may approach community leaders who are known to be opinion leaders. RHCP community partners and interventionists from the HIF study will explain the study and HP role. Second, HPs may be selected by RHCP community partners from opinion leaders identified in the network analysis. Participants were asked to name the top people they go to when they need advice, both in general and for specific advice about diet, physical activity, and weight loss. Both *degree centrality*, the measure of incoming and outgoing ties to a person in a network, and *betweenness centrality*, a measure of the extent to which a person lies on the shortest path in the network, were assessed as part of the identification process for the HPs. To maximize potential effectiveness of the intervention, the HP identification strategy was contingent upon certain network characteristics, namely *modularity*. Modularity is a measure of the structure of a social network, and measures the strength of the division of a network into ‘modules’ or sub-groups. A network with high modularity would have dense connections between people within sub-groups, but sparse connections between



people in different sub-groups.^{132,133} We calculated the modularity of the community sample to determine the strength of sub-group structure. We determined a priori that if modularity was high (>0.3), then HPs would be recruited from the leaders identified within these sub-groups, even if they were not the most nominated opinion leaders for the overall network. The rationale for this strategy is that in a social network with many close sub-groups, the intervention will be most meaningful coming from a leader within a participant's own close sub-group. If modularity was relatively low (<0.3), then HP's would be recruited from those with the highest degree and betweenness scores in the advice networks.^{134,135} Our social network data demonstrated that the modularity for the Hispanic network was 0.94 and 0.75 for the Somali network, indicating based on our a priori criteria that HPs should be drawn from the most influential individuals within sub-groups rather than individuals with a combination of high in-degree and betweenness centrality in the overall network.

Training of Health Promoters. We have recently described the training procedures for interventionists for the HIF study.¹³⁶ For this project, the training was streamlined to account for delivery in networks, thereby enhancing intervention scalability. In the HIF intervention we learned that while startup training is important, ongoing training and supervision is crucial. The HPs and the intervention oversight clinicians met every two weeks for one hour to review the content for the next two sessions and to answer questions related to the ongoing groups. We will also train health promoters on how to access and use the WellConnect portal to enter and track participant participation.

Participants, Recruitment, and Enrollment

Health Promoters will invite members of their social networks to participate in the study. We will limit network participants to a maximum of 12 per HP for purposes of measurements and the mentorship/education portion of the intervention. Eligibility criteria include (1) self-identification as Hispanic or Somali, (2) member of a social network identified in the social network analysis, (3) age ≥ 18 , (4) willingness to participate in all aspects of the study; and (5) provision of informed consent. Exclusion criteria include (1) pregnancy at the time of enrollment and (2) serious medical conditions or disabilities that would make physical activity difficult. To avoid stigmatization, a normal weight (BMI < 25) will not exclude individuals from participating in the intervention, but they will be excluded from the measurements and analyses. Based on our network analysis, we expect 81% of Hispanic and 50% of Somali participants screened to be overweight or obese. When an HP identifies an individual, they will accompany a language-congruent study assistant and study coordinator to their home or community location, where eligibility will be determined, and informed consent and baseline measures will be obtained. Based on our preliminary data, we will not restrict the participants to a particular age group for either population, as there was no significant clustering found by age. Likewise, network data, and community feedback, have helped to determine that we will not restrict Hispanic groups to gender concordance, but Somali groups will be gender-concordant, due primarily to cultural and religious beliefs and practices. Our social network data also indicate that 81% of Hispanic participants and 94% of Somali participants were immigrants born outside the US. The 19% of Hispanic and 6% of Somali immigrants born in the US were all first-generation immigrants (i.e., their parents were born outside the US). While this study targets foreign-born immigrant populations, US-born members of social networks will not be excluded.

Study Participants will receive four \$75 gift cards, one for each measurement time: baseline, 6 months measures, 12 months measures, and 24 months measures. The health promoters will receive up to \$100 for participating in training, \$600 for delivering the program during the first 6 months, and \$300 for delivering the program in the second 6 months.

Interventions

The multi-level intervention will consist of community-based mentoring and education delivered by trained Hispanic and Somali HPs to their social networks. Over a period of 6 months, HPs will facilitate 12 face-to-face or virtual group visits. Each of the twelve sessions will target a particular behavior for weight loss and/or reduction of cardiovascular risk (Table 3). All sessions will include goal setting, review of food and/or activity tracking, and



positive reflections. Specific strategies for weight loss include regular weigh-ins, completion of food and physical activity records, reducing portion sizes, planning meals, use of MyPlate for dietary proportions, removing problem foods from the home, increasing physical activity level, and reducing sedentary behavior. MyPlate was selected for this intervention since the materials are available to individuals at no cost, the information is presented in several languages, and participants in the HIF intervention rated MyPlate highly.

Consistent with the theoretical framework, HPs will provide support and monitor progress on goals via six evidence-based strategies: Tracking, Goal Setting, Mindfulness, Social Support, Problem Solving Skills and Motivational Strategies.¹³⁷ Participants will be informed that one of the goals is for a weight loss of 3% in overweight or obese individuals. Additional goals included reduction of portion sizes of calorie dense foods, a shift of relative dietary content to increase fruit and vegetable consumption, and 150 minutes per week of moderate to vigorous physical activity.

Over the subsequent 6 months, HPs will facilitate an additional 12 virtual or face-to-face maintenance sessions to focus only on goal setting, review of food and/or activity tracking, and positive reflections (i.e., no new content will be delivered).

Table 3. Intervention outline and session topics

Weekly Group Session Outline	Content for Weekly Group Sessions
<ul style="list-style-type: none"> • 5 minutes: Welcome • 5 minutes: Review of goals from prior week • 10 minutes: Review of food and/or activity tracking • 15 minutes: New weekly topic • 20 minutes: Set SMART* goals for the following week • 5 minutes: Positive reflections <p>*Specific Measureable Achievable Relevant Timely</p>	<ol style="list-style-type: none"> 1. My Plate; SMART goal setting; Food tracking 2. My Plate: fruits and vegetables; Weigh-ins; Activity tracking 3. Triggers for over-eating; Mindful eating 4. Sugars in food and beverages; How to be physically active 5. Fats; Healthy cooking strategies 6. Importance of physical activity 7. Social support 8. Stress eating; Mindful eating 9. Loss of control; Managing problem foods; Social eating situations 10. Planning healthy meals 11. Self-compassion with eating 12. How to keep going long term
Group Session Goals	Group Session Strategies
<ul style="list-style-type: none"> • Reduction of portion size (My Plate) • Shift of relative dietary content to My Plate proportions (i.e., 50% fruits and vegetables) • 150 minutes per week of moderate to vigorous physical activity • 10,000 steps per day 	<ul style="list-style-type: none"> • Food records • Physical activity trackers • Weight monitoring • SMART goal setting • Feedback and re-enforcement • Modeling and social support • Problem solving • Self-efficacy enhancement

Intervention guide. The study team, with RHCP community partners, has developed an intervention guide that will be printed and made available on the RHCP web site and within the program leader space on WellConnect. The guide consists of 3 sections: Section 1 includes the 12 content modules. Section 2 includes principles of facilitating evidence-based cognitive-behavioral techniques for healthy behaviors: goal setting, feedback/reinforcement, self-efficacy enhancement, modeling, and problem solving.¹³⁷ Section 3 includes a list of low or no cost community resources for physical activity and healthful eating.

The programmatic intervention dose is lower than many health promotion interventions. The rationale is that 1) the intervention will be more impactful when delivered by a member of participant's social network,¹³⁸ and 2) non-programmatic health promoting activities and interactions are likely to occur within and between social networks (indirect intervention effect) throughout the study interval.¹³⁹ This approach highlights the potential advantages of social network interventions for scalability and sustainability.^{70,140}

The rationale for the mentorship and education component of the intervention arose from the success of this model in the Healthy Immigrant Families study, where the interventionists were not necessarily members of participant's social networks. For this application, mentorship has the potential to carry more influence through



delivery within social networks by respected peers. Peer mentoring has been shown to be effective in promotion of healthy eating and physical activity among groups with low socioeconomic position.^{141,142}

Treatment Fidelity & Measures

Treatment Fidelity

In the design and conduct of this study, we have incorporated recommendations from the Treatment Fidelity Workgroup.¹⁴³ We have recently described our process for assessing treatment fidelity for community-based behavior change interventions with immigrant groups in a CBPR framework.¹³⁶ The HPs will utilize a manual (phase 1) containing an outline/script for each session and a checklist of critical topics to be covered at each session. Study assistants, who were interventionists for the Healthy Immigrant Families study, will randomly observe 5% of sessions with the HPs. These study assistants have developed expertise as health behavior change interventionists through 250 hours of training followed by two years of intervention delivery.¹³⁶ They will be further trained in fidelity assessment for this study, thereby addressing the barrier of language concordance between interventionists and assessors. Bi-weekly meetings will be held with the HPs and study team to reinforce treatment fidelity, provide corrective feedback, and to conduct additional training if needed.

Measures

Data will be collected at 0 (baseline), 6, 12 (primary endpoint) and 24 months by trained study staff blinded to treatment condition. Participants will complete a survey and participate in physical measurements.

Demographic, acculturation, and structural racism measures. The following demographic data will be collected at baseline: age, gender, ethnicity, country of birth, annual household income, education level, employment status, and use of social media. Participants will report on the following proxies for acculturation: years lived in the US, primary language spoken at home, and level of English language proficiency on a 5-point Likert scale.¹⁴⁴ Degree of dietary acculturation¹⁴⁵ will be assessed from results of 24-hour dietary recall described below. The following measures of structural racism will be obtained at baseline: Home address for automated collection of geolocation-based measures (Minnesota Measure of Structural Racism [MMSR], Area Deprivation Index [ADI], County Structural Racism Index); Everyday Racism Scale, Discrimination in Medical Settings Scale, and Medical Mistrust Scale.

Primary outcome measures.

BMI: Weight will be measured to the nearest 0.1 kg using a portable scale (Seca 880 Digital Floor Scale). Height will be measured to the nearest 0.1 cm at baseline only using a stadiometer. Participants will be asked to remove shoes prior to both measurements. BMI is calculated as weight (kg)/height squared (m²). Waist circumference will be measured to the nearest 0.1 cm at the narrowest part of the torso between the ribs and the iliac crest. Participants will remove excess clothing prior to the measurement and smooth the remaining clothing against the skin. Two measurements will be taken; if the difference between the two measures is more than 2.0 cm, a third measurement will be taken. The average of the two closest measures will be used.

Secondary outcome measures. The secondary outcome measure will be the "Life's Simple 7" Composite Score, which is adapted from the American Heart Association standards based on health assessment data¹⁴⁶: average blood pressure from 3 readings, fasting lipid panel and glucose, height, weight, self-reported cigarette smoking status, dietary quality, and physical activity patterns). Point values are assigned to each component: 2 points for ideal, 1 point for intermediate, 0 points for poor. The total sum allows for a continuous measure of cardiovascular health ranging from poor to ideal (0-14 points). The final score will be categorized as 0-6 (poor), 7-8 (intermediate), 9-14 (ideal). In previous studies, adherence to the ideal Life's Simple 7 metrics was found to be associated with decreased risks of cardiovascular disease¹⁴⁷ and all-cause mortality¹⁴⁸.

Seated blood pressure (systolic and diastolic) measurements will be made on the right arm using an automated BP Tru BPM-200 after sitting quietly for five minutes.¹⁴⁹ Blood pressure will be measured three times and the average of the second and third readings will be used in analyses. Fasting glucose and cholesterol will be collected by a single finger prick obtained by Mayo Clinic CRU staff. Participants will be asked to refrain from eating for at least 6 hours prior to testing. The portable Whole Blood Lipid Screen Cholestech LDX Analyzer will



be used to analyze specimens, which combines enzymatic methodology and solid-phase technology measured by reflectance photometry to measure total cholesterol, HDL cholesterol, triglycerides and glucose in whole blood. LDL cholesterol is a calculated value. Samples used for testing are whole blood from a fingerstick collected in a lithium heparin coated capillary tube. Results will be recorded at the site of collection and samples will be destroyed upon recording of results.

Dietary Quality: Two 24-hour dietary recalls will be collected using the Automated Self-administered 24-hour Recall (ASA24) system, a National Cancer Institute web-based tool that enables multiple automated self-administered 24-hour recalls. The recalls will be performed using a computer under the supervision of study staff. The tool is available in English and Spanish. A study staff member and an interpreter will complete the recall with participants who speak other languages. Through these intake estimates, the effect of the intervention on diet quality (Healthy Eating Index plus intake of fruits, vegetables, sweetened beverages, percent energy from fat and total calorie consumption) may be examined.

Physical activity: The International Physical Activity Questionnaire (IPAQ) ¹⁵⁶ will be used to assess the number of minutes of mild, moderate, and vigorous physical activity over the previous 7 days. We have used objective measures of physical activity in past studies (accelerometers) as a primary outcome,⁴⁴ but for this study the survey will be used only to observe changes over time, not as an objective measure of activity.

Table 4. Life's Simple 7 domains and derivation of its composite score¹⁵⁷⁻¹⁵⁹

"Life's Simple 7" Domain	Optimal (2 points)	Intermediate (1 point)	Poor (0 points)
Weight	BM<25	BMI 25-29.9	BMI ≥30
Blood pressure	SBP<120 and DBP<80	SBP 120-139 and DBP 80-89	SBP≥140 or DBP≥90
Total cholesterol	<200 mg/dL	200-239 mg/dL	≥240 mg/dL
Fasting glucose	<100 mg/dL	100-125 mg/dL	≥126 mg/dL
Smoking status	Never or quit >12 months ago	Former or quit ≤12 months ago	Current
Diet	HEI≥69.3	HEI 56.9-69.2	HEI<56.9
Physical activity	≥150 min/wk moderate or ≥75 min/wk vigorous or ≥150 min/wk moderate+vigorous	1-149 min/wk moderate or 1-74 min/wk vigorous or 1-149 min/wk moderate+vigorous	None
Composite Score	9-14	7-8	0-6

Health-related Quality of Life will be measured by single-item linear analog scale assessments of physical, emotional, and overall health developed by members of our research team^{160,161}.

Theory-based measures. Survey items will be used to assess self-efficacy and social support for diet and physical activity that were adapted for our HIF study from instruments developed for the Patient-centered Assessment and Counseling for Exercise plus Nutrition (PACE+) program for low-income, ethnically diverse adults¹⁶² that included nutrition self efficacy¹⁶³ and social support,¹⁶⁴ physical activity self efficacy¹⁶³ and social support.¹⁶⁴ Test-retest reliabilities and internal consistency reliabilities were acceptable for all of these constructs, and association with behaviors suggested criterion-related validity^{163,164}. A 6-item measure of group social cohesion with excellent reliability (Cronbach alpha 0.95)¹⁶⁵ used in previous network intervention studies and in our pilot studies¹³⁰ will be used to assess this. Number of social contacts trying to lose weight and social norms for weight loss will be assessed using a 4-item measure with good to excellent reliability and item loadings.⁶¹

Validity concerns for survey instruments. While all scales described above to measure theory-based outcomes carry adequate validity evidence, the application of these instruments to our culturally and linguistically heterogeneous population is problematic. In the HIF project and social network analysis (see Preliminary Data), we minimized this limitation through editing of the English-language version of each item with community partners from both groups for cultural relevance, followed by forward-translation, panel discussion, backward translation, a pre-test, a cognitive briefing and consensus on the final version by a core group of community members from each group (to reflect an accurate translation and cultural appropriateness).¹⁶⁶ We have previously described this process of adapting the World Health Organization translation procedure for use with survey instruments in a CBPR framework.¹⁶⁷ We used this approach for all survey measures outlined in this proposal, and have applied them to two studies.^{103,104}



Diffusion and contamination measurement. Network interventions broadly work through social diffusion of behavior change through social networks.⁷¹ Diffusion can also be conceived as contamination if it occurs from an intervention group network into a control group network.¹⁶⁸ Indeed, randomized controlled trials of social network interventions tend to underestimate intervention effects because of contamination.^{71,169,170} To assess the potential impact of contamination on the evaluation, we will measure diffusion of content to the intervention group and control (contamination) group through methods outlined by Simmons, et al.¹⁶⁹ We will assess whether specific terminology associated with the intervention modules were recognized by network participants in both groups. Recognition of negative control terms (health promotion terms not associated with the intervention or with obesity/weight loss) will also be assessed in both groups for comparison. The difference between diffusion of intervention terms and negative control terms in both groups (intervention and control) will provide a measure of diffusion in both groups and therefore contamination in the control group.

Measurement protocol and staff training. Participants from individual social networks will be measured in the same time-frame with the HP organizing times and locations. The measurement team will consist of one or two language/culture-concordant study assistants and the study coordinator. The study assistants will be responsible for administering the dietary recalls and the questionnaire. The study coordinator will be responsible for overseeing biometric measures.

Randomization & Sample Size Considerations

Randomization

The units of randomization will be social network subgroups. Randomization will occur after all HPs and their social network participants are enrolled and baseline measures are completed. Randomization will be stratified according to ethnicity (Hispanic or Somali), age, and sex of the HPs as well as group size.

Social network sub-groups are sufficiently discrete for randomization: Our social network data analysis determined that these communities were composed of enough discrete sub-groups for randomization. An example of this is that the Hispanic network had 144 unique sub-groups. When considering only sub-groups composed of five or more individuals, there were still 88 sub-groups identified using modularity calculations. This is a sufficient number of sub-networks for randomization, especially when considering the approximately equal number of Somali networks. Therefore, the high clustering observed in our preliminary data, as demonstrated by the high modularity of the networks, indicates that there are clearly distinct subgroups in the networks and that randomization via subgroups is feasible and appropriate for the study.

Sample size considerations

Stepped wedge cluster randomization trials typically have more statistical power than other cluster randomized designs.¹¹⁵ This is because each cluster is able to serve as its own control, accounting directly for the within cluster correlation of outcomes. In addition, the impact of intra-cluster correlation on power is typically smaller than on conventional cluster randomized trials.¹⁷¹ For the current study, we expect each HP to recruit 6 to 8 participants, so assume 7 per cluster and a substantial loss to follow up of 20% over 12 months. We assume a conservative intra-cluster correlation in outcomes of 0.10 to calculate the design effect DE_{sw} based on the formula:^{115,171}

$$DE_{sw} = \frac{1 + \rho(ktn + bn - 1)}{1 + \rho\left(\frac{1}{2}ktn + bn - 1\right)} \cdot \frac{3(1 - \rho)}{2t\left(k - \frac{1}{k}\right)}$$

where $k = 2$ is the number of steps (including baseline), $b = 1$ is the number of measurements per subject in the baseline step, $t = 1$ is the number of measurements per subject at each step, and $n=7$ is the number of subjects per cluster. Assuming 80% follow up and equal

distribution across clusters, and a 80% power, we estimate the detectable standardized effects (SDs) for a range of numbers of enrolled HPs with a maximum probability of a Type II error of 0.05.

SD	HPs	N total
0.1	478	1673
0.2	120	420



0.3	53	187
0.4	30	106
0.5	19	68
0.6	14	48

For the primary endpoints, a third standard deviation (0.3SD) difference between groups will be considered clinically meaningful.¹⁷² On the basis of the previous Healthy Immigrant Families study, we will assume a 0.1 standard deviation change in the control group ("contamination") so this represents a 0.4SD change in the intervention group. Therefore, the study will accrue 54 clusters (27 per group) with

approximately seven participants in each cluster, for a total sample size of approximately 378 network participants.

Data Analysis

All analyses will be appropriate for stepped wedge trials. In the direct effects model, the co-primary endpoints will be changes in BMI and waist circumference from baseline to month 12 and the 12-month change in the Ajzen TPB, the common outcome for C2DREAM. We will use mixed effects regression models to adjust for correlations within social network clusters and over time.¹¹⁴ Models will include indicators for intervention status, step, and their interaction. Covariates indicated above including demographics (e.g., sex, years since arrival to the US) and social covariates will be included in profile analysis models to assess the sensitivity of the primary analysis conditional on these potential concomitant (mediating) influences. All secondary endpoints will be analyzed using the same methods as used for the primary endpoints.

Missing data will be handled in several ways using an extensive library of macro procedures designed specifically for such tasks by the Mayo Clinic Division of Biostatistics.¹⁷³ Simple imputation methods such as minimum, average, or maximum values carried forward will be followed by multiple imputation methods to assess the robustness of the study results in the presence of the missing data. All models will be assessed for goodness of fit, with effects reported with confidence intervals. All hypothesis tests will use $\alpha = 0.05$ to determine significance.

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