Cluster Randomized Controlled Trial to Promote Physical Activity Among Low-resourced Mothers in New York City: Protocol for the Free Time for Wellness (FT4W) Effectiveness Trial

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Study Purpose and Rationale:
Physical activity can reduce the risk of chronic diseases, yet there are many structural barriers to being active, including low socioeconomic position (SEP). More than 60% of women of low SEP in the US do not reach the recommended guidelines of at least 150 minutes of moderate physical activity each week. Low SEP mothers are at high risk for chronic diseases and have an increased burden to improve health behaviors due to challenges such as limited time, resources, and access to safe neighborhoods. At the same time, mothers are a powerful group—they make decisions that affect family health and model behavior for their children. If given the right resources, investment in maternal health is an investment more broadly in community health. However, most physical activity interventions do not leverage community-level resources to enable individual-level change. Nor do they consider how intersectionality may play a role. There is a need for innovative interventions targeted at communities with high social inequality, where risk of chronic disease is quite significant and there is equally significant potential to positively impact health and health disparities. To address this need, we will test a first-of-its-kind intervention that we co-designed and piloted with mothers for mothers that provides free childcare in combination with a novel peer support system. No prior health intervention has included these components, which we hypothesize (based on prior theory and our own pilot work) will increase physical activity. We bring this together with the growing body of research on social cohesion, which suggests that individual adoption of health behavior is much more likely when participants receive social reinforcement from multiple neighbors in their social network. Our co-designed intervention, the Free Time for Wellness (FT4W) program, will generate novel access to individual and community-level resources and will leverage peer support among mothers in urban, racially segregated, low-income communities.

The broad objective of this proposal is to test the effectiveness of FT4W, an innovative multilevel physical activity intervention to increase physical activity and ultimately reduce the risk of chronic diseases and improve mothers' wellbeing.

Study Design:
We will evaluate the FT4W program using mixed methods in a three-arm parallel cluster RCT that will enroll 90 mothers aged 18 years living in areas of high social inequality. The study will be conducted at 3 community-based fitness class locations affiliated with an established and sustainable city-run free fitness program, Shape Up NYC. The fitness classes are located in neighborhood health action centers that serve populations that are minoritized racial/ethnic groups and less privileged socioeconomically, with stark health disparities including premature mortality. The primary outcome of interest is an increase in moderate to vigorous physical activity within 12 weeks, measured at baseline and follow-up. Concurrently, we will examine how individual, community, and institutional level factors modify and influence the overall effectiveness of the intervention through embedded qualitative method throughout the trial. Ethnographic will be collected at the intervention sites during recruitment, randomization, intervention, and follow-up, in combination with interviews with stakeholders,

Methods:
Intervention

The Free Time 4 Wellness intervention entails free fitness classes with accompanying free childcare and peer support activities including group text messaging, play dates, and food pantry volunteer and visits. To assess effectiveness there will be 3 arms: Arm A will receive access to fitness classes, Arm B will received free fitness classes and childcare, Arm C will receive free fitness classes, childcare and peer support activities Participants in all arms will also participate in research procedures including survey completion, accelerometer wearing.

We will conduct the intervention in 3 Shape Up NYC sites which are located in NYC parks and recreation facilitates. The 3 sites will be randomized into one of 3 arms with 8 sites in each arm. We will recruit 30 participants into each arm.

Survey and Accelerometer

All participants will be provided with a participant information sheet and will provide informed consent before

taking part in any research activities. All participants will be asked to complete baseline measures including an online survey and will be mailed a concealed physical activity device to be worn for 8 days prior to accessing the exercise class facilitated by Shape Up (all Arms). All participants will be asked to complete another online survey and wear the activity monitor for a further 8 days in the final week of the 12 week program (all arms). The survey will include validated scales to gather overall health status and wellbeing. The survey is housed in web-based data management system created and hosted by the Data Management Unit (DMU) of the Department of Biostatistics in Columbia University's Mailman School of Public Health and hosted on CUIMC IT-certified secure servers. The data system serves as the central information hub for the project, and will collect all study related data expect for qualitative materials and data. The physical activity device will gather total minutes spent in moderate to vigorous intensity physical activity, sedentary time and sleep using a concealed device. We will gather identifiable and personal information such as age and contact details in order to distribute study materials (physical activity device) and facilitate the delivery of the intervention.

Text Messaging

All participants will receive text message notifications via Ring Central reminding them of upcoming exercise classes and research components. Ring Central is a customer engagement platform that allows users to send programmable SMS and MMS. Participants will receive messages using Ring Central's Programmable Messaging API which will deliver one-way, transactional messages. Arm C, there will be additional text messages about the play dates, volunteer days, food delivery and community building. These text messages will follow suggested scripts and be sent by community champions.

Childcare

Those in arms B and C will have access to free childcare at the same time as their participation in the exercise classes. Jovie is a professional childcare company that provides sitters for families and businesses. Jovie performs background and reference checks and educates each sitter who works at Jovie. Parents will sign waivers with Jovie to allow for their child to be in their care during the duration of the fitness class.

Food Pantry

Those in arm C will also have access to WSCAH, which is one of the largest food pantries that serves New York City and facilitated play dates to encourage peer support and social cohesion. Some participants (Arm C), will have the option to receive food box deliveries to their homes for free over the course of the 12 weeks.

Play dates

Participants in Arm C will be offered weekly group playdates, for a total of 12 offered during the intervention. We will invite participants to bring their children to playgrounds in Shape Up NYC neighborhoods, where mothers can collectively watch their children play but also chat and reinforce social bonds.

The first two playdates will have some facilitated activities to help mothers get to know each other and to lower the social effort required to meet new people. Community Champions will also wear an FT4W t-shirt, hat, or similar to the first playdates to help participants identify the group. Activities will be split into two language groups - one in English and one in Spanish - each facilitated by a Champion. The activities will include:

Week 1: Participants will stand in a circle and will be asked to introduce themselves, to say the ages of their kids, and to say what their favorite sandwich is. The Community Champion will start and facilitate the activity. After the intro activity, participants will be free to talk amongst themselves.

Week 2: Participants will play icebreaker bingo, where the Community Champion will give them each a printed card and ask them to fill in the names of other mothers that match the statements in the boxes. They have to circulate and talk to each other to figure out which names to put where. The first person to have names in five boxes in a row (vertically, horizontally, or diagonally) will win a small prize (e.g., chocolates, FT4W swag, etc.). After the activity, mothers will be free to talk amongst themselves as usual.

In case of rain or bad weather, the playdates will be moved to the next day (Sunday morning), and if bad

weather continues, they will be canceled for that week.

For the remaining playdates, the champions will bring supplies for activities for mothers to do with their kids such as bubbles and stickers.

Community Partners

There are three community partners, Shape Up NYC, West Side Campaign Against Hunger (WSCAH), Jovie. All perform services for the intervention in line with their regular operations and will be paid through fee for service mechanisms (with the exception of Shapeup NYC who will not charge for their services). They are providing services to our research participants as part of the intervention, but none of their personnel will be performing research activities.

Fitness Classes-Shape Up NYC provides free fitness classes across NYC we will use their locations to be randomized into our intervention. Shape Up NYC will help recruit by circulating our flyer to their network and will refer our study stuff to potential participants. They have participants sign waivers. They do not collect data, but the waivers will be used for attendance tracking. Their fitness instructors will be teaching the class and are trained in mitigating any risk with moderate exercise. The classes include aerobic, dance and yoga activities.

Childcare- Jovie is a professional childcare service that will provide childcare at 16 of the NYC Shape class locations. They will have parents sign waivers to care for their children. Jovie will not collect any research data, but their waivers will be used for attendance tracking.

Food Pantry- West Side Campaign Against Hunger (WSCAH) serves any New Yorker by providing free fresh groceries. They have a mobile market model that drops food off at partnering locations across NYC as well as directly to customers' homes. They will also coordinate volunteer activities that our participants can take part in. WSCAH will not be collecting research data, but their waivers will be used as attendance tracking.

Qualitative Methods

We will also be conducting qualitative research including interviews and ethnography. Dr. Hirsch will be conducting this research along with a staff ethnographer that will be hired for the study. The ethnographer will be an affiliate of the University and once identified added to the protocol. The interviews will be audio recorded and transcribed for thematic analysis.

Interviews: The study ethnographer will interview 6 participants after the 12 week follow-up inquiring about barriers and facilitators and satisfaction. This guide will be developed using findings from the participant observation and will be developed in year 2 of the study and will be submitted for ethical approval before the interviews begin.

Participant observation: The ethnographer will also attend fitness classes at each of the 24 sites and observe interactions between participants and between participants and the instructor. The ethnographer will also attend group play dates and food pantry visits making similar observations around group dynamics. The ethnographer will take jotted notes on her phone during the session and later complete field notes immediately following each session. These notes will be coded thematically during the analysis phase.

Statistical Procedures:

We can make two major comparisons. By comparing intervention Arm B and control Arm A, we can estimate the effectiveness of providing childcare at fitness classes to increase physical activity. By comparing this effect between intervention Arms B and C, we can estimate the added effect of peer support.*Aim 1 hypothesis*: **The average time spent in moderate to vigorous physical activity will be higher in intervention Arm B vs control Arm A.** *Exploratory sub-aim hypothesis*: **This effect will be mediated by increased access to resources between baseline and follow-up.***Aim 2 hypothesis*: **The**

average time spent in moderate to vigorous physical activity will be higher in intervention Arm C vs control Arm A and intervention Arm B. *Exploratory sub-aim hypothesis*: **This effect will be mediated by increased social cohesion between baseline and follow-up.** *Aim 3 hypothesis*: **The effect of the intervention will differ by individual- and community-level stratifiers.**

Statistical analyses: The primary analyses will be on the intent-to-treat sample: all randomized participants according to the assigned treatment. Missing data on outcome variables will be dealt with by using multiple imputation or inverse probability weighting of cases with complete data, where we will calculate weights based on the probability of a participant being a completer versus a dropout. For hypotheses 1 and 2, we will use linear mixed-effects models (LMM) to assess the main intervention effects on physical activity outcomes and other secondary outcomes. The outcome measure of interest will be the dependent variable; treatment arm (categorical variable with three categories) will be the predictor. Cluster-specific random intercept will account for intra-class correlation.