CRISOL Contigo: a Multi-level Intervention to Reduce the Disproportionate Toll of COVID-19 Among Latino Communities in Philadelphia. (CRISOL Contigo)

Ana Martinez Donate,
Professor of Community Health and Prevention, Drexel University

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Statistical Analysis Plan: CRISOL Contigo Aim 2. Outreach phase.

Summary:
A community popular opinion leader (POL) based intervention to promote measures to reduce COVID-19 risk, transmission, access to testing and treatment, reduction of the impact of COVID-19, and addressing the Substance Abuse, Violence, HIV/AIDS, and MEntal health (SAVAME) syndemic in the community. POLs will interact within their networks counseling regarding COVID-19 and SAVAME factors. The POLs will refer individuals to appropriate community services. POLs will record basic sociodemographic characteristics of all community contacts, the issue addressed, and their response to it. The first 300 community contacts will be invited to complete a baseline and 3-month follow up surveys (via internet or phone). The content of the surveys includes: 1) COVID-19 related questions (knowledge, impact, symptoms, risk factors, access to testing and care, acceptability contact tracing, vaccine) 2) Biological risk factors, 3) Social determinants of health, 4) SAVAME outcomes and access to services.

Design: Quasi-experimental (pre-post), pragmatic, single arm, non-randomized, study.

Evaluation of this intervention will be guided by RE-AIM, a comprehensive evaluation framework to gauge a program's public health impact.
Below we outline the Statistical analysis plan of the individual-community contacts level.
The two co-primary outcomes will be:

1) Changes in risk of exposure to COVID-19, defined as the availability and/or usage of five modifiable risk factors: Use of mask, frequent hand washing, compliance with physical distance, avoidance of contact with high risk individuals. Combined (added) to create a score. [Time Frame: Baseline and 3 months]
2) Number of participants who lack access to health care [Time Frame: Baseline and 3 months]

Secondary outcomes include:

1) Number of participants with SAVAME-related factors [Time Frame: Baseline and 3 months]
2) Number of participants who lack access to health care [Time Frame: Baseline and 3 months]

Statistical analysis plan.

Baseline and demographic characteristics will be summarized overall for all patients and for those with complete follow up. Univariate summary statistics will be provided for continuous variables and frequencies for categorical variables. Paired t-tests and test of proportions, will be used to assess changes in these outcomes from baseline to 3 months.