Adapting a Low-cost Intimate Partner Violence (IPV) and Mental Health Response Intervention for Women in Informal Settlements in Kenya

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BACKGROUND

Study Purpose and Rationale

Violence against women (VAW) is a critical determinant of mental health for women.1 Globally, 30% of women have experienced intimate partner violence (IPV).[2] Women who experience IPV are more likely to experience depression, anxiety, and post-traumatic stress disorder (PTSD).[3] Furthermore, common mental disorders (CMDs) can increase risk of IPV victimization.[4] In Kenya, interpersonal violence ranks in the top ten causes of morbidity and mortality.[5] Research, international and national guidelines, and policies recognize the key role of health services in the identification and response to VAW;[1,6] yet, the health system response has been slow to progress in lower- and middle-income countries (LMICs) and in disadvantaged communities.[6] Globally, one billion people live in informal settlements—defined as residential areas lacking durable housing; sufficient living and public spaces; access to basic infrastructure and other services; and secure tenancy—and this population is expected to triple by 2050.[7,8] In Kenya, approximately 20 million people (39% of the national population) live in informal settlements, and the population is still growing.[9] Research carried out in these settlements suggests that the prevalence of VAW is high and residents have the worst health outcomes of any population in the nation.[10] Estimates of IPV in informal settlements in Nairobi, Kenya, are as high as 66% in the last year[11] and 85% across the lifespan,[12] and CMDs such as depression (17%), suicide attempts across the lifespan (13%), and recent psychological distress (50%) are also high.[13,14] In 2014, Kenya incorporated reduction of VAW into their national Health Policy and Health Sector Strategic Plan (KHSSP),[15,16] and developed National Guidelines on Management of Sexual Violence,[5] which not only call for the reduction of VAW, but for interventions that screen for and respond to VAW and provide mental health services and psychosocial support to survivors. Despite the development of these strategies, screening and response protocols have not been adopted in clinics in informal settlements for survivors of IPV.[17,18]

To address the need for IPV services in informal settlements, this feasibility study proposes to test components of an IPV essential services package—defined by the WHO guidelines related to addressing IPV[19] as interventions which include identification, management, provision of first-line support, and mental health care for women subjected to IPV. Wings of Hope (WINGS), a screening, brief intervention and referral to treatment (SBIRT) program, was shown to be a

feasible, safe, acceptable, and effective intervention for reducing IPV in low-resource settings[20] and in LMICs[21] and can be delivered by non-specialists, but has not been tested in informal settlements. Research suggests that in addition to SBIRT, psychological interventions may reduce risk of further IPV victimization.[3,22,23] Problem Management Plus (PM+), a WHO intervention that is implemented by non-specialist community health volunteers (CHVs), has been effective at reducing psychological distress in women with a history of IPV in informal settlements in Kenya.[24] Given bidirectional associations between CMDs and IPV, research calls for the exploration of combined IPV and mental health response interventions to reduce IPV.[4] The purpose of this study will be to combine and adapt WINGS and PM+ and to assess the feasibility and acceptability of WINGS+PM+ as the foundation for a low-cost, IPV services package to reduce IPV for women in informal settlements in LMICs where access to IPV and mental health services is limited.

Research Aims & Questions

RQ1: Is the combined, adapted WINGS+PM+ pilot intervention feasible, acceptable, and safe? What is the fidelity of the pilot?

RQ2: What are the effects of the WINGS+PM+ versus PM+ only intervention on participants' IPV self-efficacy, social support, safety, receipt of IPV services, psychological distress, functioning, PTSD and personally-identified problems?

RQ3: What are the effects of the WINGS+PM+ versus PM+ only intervention on incidence/severity of IPV?

STUDY DESIGN

The proposed project consists of a five-year, three-phase project implemented by non-specialist health staff and CHVs at health clinics in Kibera and Mathare. Guided by the community intervention planning framework (CIPF), the project will adapt, refine, and pilot the combined WINGS+PM+ intervention as a potential foundation for a low-cost, IPV services package for healthcare settings in informal settlements. This project is for a K01 training grant; thus, each study phase is linked with the grant training objectives and will be accomplished in collaboration with mentors.

AIM 1/PHASE 1: Identify potential facilitators and barriers to screening and intervention for IPV and mental health in healthcare settings in informal settlements. Qualitative in-depth interviews with N=30 staff at two public health clinics (15 staff at each clinic) and N=36 survivors of IPV (18 in Kibera and 18 in Mathare), and focus group discussions (FGDs) with community health volunteers (CHVs) (N=24: 12 in Kibera and 12 in Mathare) will be conducted to identify facilitators and barriers to IPV/mental health screening and intervention in two large informal settlements (Kibera and Mathare) in Nairobi, Kenya.

AIM 2/PHASE 2: Combine WINGS and PM+ and adapt the combined intervention for use in healthcare settings in informal settlements in Nairobi. Guided by the collaborative intervention planning framework (CIPF),[25] workshops with a local community consultation group (CCG) and meetings with a community advisory board (CAB) will be conducted to combine/integrate core elements of WINGS and PM+ and adapt the combined intervention (WINGS+PM+) for implementation in existent healthcare settings in informal settlements in Nairobi.

AIM 3/PHASE 3: Pilot test WINGS+PM+ through a randomized control trial (RCT). With N=260 women (n=130 in Kibera and n=130 in Mathare) we will pilot the WINGS+PM+ intervention to assess the safety, feasibility, and acceptability of WINGS+PM+ (n=130: 65 in Kibera and 65 in Mathare) vs. PM+ (n=130: 65 in Kibera and 65 in Mathare). Following WHO recommendations and national efforts to expand service provision to low-resource communities by adopting task-sharing models of select service provision and mental health care in Kenya,[17,26] CHVs will be trained to implement WINGS+PM+. Pre- and post-tests and 3- and 6-month follow-ups will be used to obtain preliminary estimates on program mediators (e.g., IPV self-efficacy, social support, psychological distress outcomes) and reduction of IPV (distal outcome) in the WINGS+PM+ intervention arm vs. PM+ only.

WINGS is an SBIRT intended to be carried out by non-specialists (e.g., CHVs). It involves two 1-hour, weekly sessions focused on exploring types and mechanisms of IPV (e.g., the role of household economics in IPV), building motivation to address IPV, safety planning and revision, enhancing social support to address IPV, goal setting and revision, identifying IPV-related services and needs, linkage and referral to services, and self-care planning. PM+: is a brief psychological intervention carried out by non-specialists (e.g. CHVs) and focused on problem management and evidence-based behavioral strategies to enhance one's capacity to adaptively manage psychological distress. PM+ involves five 90-minute, weekly individual sessions focused on

learning and practicing a stress management technique; identifying, defining, and managing problems through goal setting and review; increasing engagement in positive activities; strengthening social supports; and developing plans to stay healthy and well beyond the intervention. PM+ uses a practical, problemmanagement approach to psychological intervention that can be adapted to focus specifically on IPV-related problem-solving. Baseline assessments, the adapted WINGS+PM+ and PM+-only interventions, and follow-up will be carried out by CHVs in Mathare and Kibera. Participants in both arms will be assessed at 4 time points: baseline, immediately post intervention (IPI), and 3- and 6- months post intervention.

Study procedures

The proposed study will take place in three phases: 1. formative, 2. adaptation, and 3. pilot test.

Pilot Test Phase (n=260): In Phase 3 of the project, 130 women who screen positive for recent IPV at Kianda 42 and 130 who screen positive for recent IPV at Upendo will be invited to participate in a pilot trial of the adapted WINGS+PM+ intervention. Participants at both clinics will be randomized to either the WINGS+PM+ (n=65 at Kianda 42/n=65 at Upendo) or PM+-only (n=65 at Kianda 42/n=65 at Upendo) arms. We will assess mediating program outcomes for WINGS (IPV self-efficacy, social support, safety, receipt of IPV services) and PM+ (psychological distress, functioning, PTSD and personally-identified problems) and incidence/severity of IPV (distal outcome) (see Table 4 for measures). Non-specialist health workers (in-take staff/nurses) at Kianda 42 and Upendo clinics will be trained to screen for IPV and CHVs to administer PM+ and WINGS+PM+, and to carry out assessments. We will assess feasibility, acceptability, fidelity, safety, and preliminary estimates of IPV.

In-take staff/nurses will screen consenting, female-identifying patients for recent IPV (past 90 days) using the WHO IPV-BSS5 as part of the regular in-take process at the Kianda 42 Clinic in Kibera and Upendo in Mathare. If women screen positive for recent IPV, they will be referred to a trained CHV who will provide them with an oral description of the pilot test and, if they wish to participate and provide informed consent, administer the baseline assessment, and set them up with a CHV who will administer the PM+-only or a CHV who will administer the WINGS+PM+ intervention based on the random assignment given by the PI or RA. Block randomization will be used to randomize participants to either the adapted WINGS+PM+ intervention arm (n=65 at

Kianda 42/n=65 at Upendo) or a PM+-only arm (n=65 at Kianda 42/n=65 at Upendo). Participants in the adapted WINGS+PM+ intervention arm will immediately receive the first of two 1-hr sessions of WINGS (1. Knowledge building, safety planning, social support, goal setting, and referral to services) and subsequently receive the second session of WINGS (2. Review, goal revision, utilization of services) a week later and five 90-min individual sessions of PM+ (1. Stress management, 2. Problem management; 3. Increase activity levels; 4. Strengthen social support; 5. Staying well and looking forward) over the course of 5 weeks. CHVs trained using the adapted WINGS+PM+ training and intervention manuals will provide the 7, weekly adapted WINGS+PM+ sessions. Participants in the adapted PM+-only arm will immediately receive the first 90-min individual sessions of PM+ (1. Stress management) followed by the four, 90-minute weekly sessions of PM+ (2. Problem management; 3. Increase activity levels; 4. Strengthen social support; 5. Staying well and looking forward) over the course of 5 weeks. CHVs trained using the adapted PM+-only and combined, adapted WINGS+PM+ training and intervention manuals will provide the weekly adapted WINGS+PM+ and PM+-only sessions. These sessions will be audio recorded. Participants in both the adapted WINGS+PM+ intervention arm and the PM+- only arm will participate in an immediate post-intervention (IPI) assessment directly following completion of the WINGS+PM+ or PM+-only interventions. Subsequently all participants in both arms of the study will be asked to participate in follow-up assessments at 3-months and 6-months.

The pilot phase involves assessing the adapted WINGS+PM+ intervention for feasibility and acceptability at the Kianda 42 Clinic in Kibera and Upendo in Mathare. Consenting women (see Informed Consent and Assent section for details) will be screened for recent IPV in the outpatient, in-take department at Kianda 42 and Upendo clinics using the WHO IPV-BSS.5 Consenting women who then screen positive for recent IPV (see Informed Consent and Assent section for details) will be asked if they are interested in participating in the longitudinal study. If they express interest, they will be screened for additional study eligibility/safety (see Eligibility Criteria section for details). Eligible participants will be taken through the informed consent process, asked to provide written consent, given a baseline assessment, and subsequently randomized to one of the two intervention arms: (1) adapted WINGS+PM+ (n=65 at Kianda 42/n=65 at Upendo) or (2) adapted PM+-only (n=65 at Kianda 42/n=65 at Upendo).

STATISTICAL PROCEDURES

This feasibility study, while not powered to detect significant changes in all outcomes, will provide insight into key process measures (e.g., feasibility, acceptability, safety, and retention) and generate data on distributions of study outcomes to enable us to calculate the power to detect a meaningful effect size in a future efficacy trial. This aligns with guidelines for a sequential approach to developing and adapting behavioral interventions. We estimated power for this study based on findings from previous WINGS and PM+ studies. Based on power analyses and attrition rates for previous trials we estimate attrition to be no more than 30%. Power analyses were conducted with G*Power (v3.1.9.2) using a repeated measures within-between ANOVA approach and =0.05. With 49 women per arm at each clinic site, we will have power to detect a medium effect size (f=.15) in sub-population analyses. Thus, we will recruit 130 women per clinic (260 total) and aim to have 98 for analysis in clinic sub-population analyses.

The primary purposes of a pilot study are to demonstrate safety, acceptability, and feasibility of methods and to determine important parameters with sufficient accuracy to allow reliable estimates of sample size, power, and detectable effects for a subsequent large-scale trial. This pilot study aims to ensure that the parameters for the larger trial are estimated as informatively as possible. We will estimate key study effect parameters with sample means and proportions together with 95% confidence intervals and test the primary null hypothesis at the two-sided level.

We will examine effectiveness of the WINGS+PM+ intervention on program mediating outcomes and incidents/severity of IPV (distal outcome) at the patient-level. Generalized linear mixed-effects models will be used to estimate whether changes in each outcome significantly differ from baseline at the 3- and 6-month follow-up. We will construct simple summaries (means and standard errors/deviations for continuous, normally distributed variables, medians and interquartile ranges for continuous, skewed variables and frequencies/proportions for categorical variables) to characterize patient characteristics, as appropriate. Characteristics significantly associated with participation will be adjusted for in the analyses.

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