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Nguvu: Evaluating an integrated approach to reduce intimate partner violence and psychological distress in refugees in Tanzania

Submission date
13/06/2016

Recruitment status
No longer recruiting

Registration date
27/06/2016

Overall study status
Completed

Last Edited
10/07/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Plain English summary as of 07/11/2018:
Background and study aims
Intimate partner violence is a major concern in refugee camps, as well as putting people at risk of mental health issues such as anxiety and depression (psychological distress). Studies have shown that psychological distress and intimate partner violence are directly related, in that intimate partner violence causes worse mental health and in turn mental health issues can increase risk of further intimate partner violence. It can be very difficult to break this cycle, and so an approach that addresses both mental health and the violence is necessary (integrated approach). The Nguvu (Kiswahili for strength and energy) project is an integrated approach designed to address these issues, through a combination of empowerment (providing information, discussing options and helping women make safe and informed choices to reduce violence) and psychological support (reducing emotional difficulties resulting from violence exposure). The aim of this study is to assess the relevance, acceptability and feasibility of a future definitive randomized controlled trial (RCT) evaluating the efficacy of an integrated intervention to reduce psychological distress and intimate partner violence for adult refugee women.

Who can participate?
Women who are refugees from the Democratic Republic of the Congo (DRC) currently living in Nyarugusu Refugee Camp (Tanzania) and participating in local women's groups who have a history of intimate partner violence and are experiencing psychological distress.

What does the study involve?
The Nyarugusu Refugee Camp is divided into seven zones for Congolese refugees, which are further subdivided into 52 villages. Local women's groups are organized within these villages and operate as opportunities for women to develop skills and strengthen their social networks. There are 59 women's groups located in zones two through seven, which are randomly allocated into one of two study conditions: usual care with and without Nguvu. Participants recruited from women's groups in the first group take part in the Nguvu program. Women's groups in zone one are not included in the trial as this served as the sampling frame for our recently completed pilot

study. The Nguvu program involves weekly sessions over eight weeks. Sessions one and eight focus on developing a safety plan and discussing issues surrounding intimate partner violence and psychological distress. Sessions two-seven focus on learning techniques to help identify stuck thoughts and learn skills to change ways of thinking that lead to psychological distress. Those living in villages in the usual care condition receive access to standard mental health and protection services during the eight week study period. This includes gender-based violence prevention and response services provided by the International Rescue Committee in Nyarugusu camp and mental health services provided by the Tanzania Red Cross. At the start of the study and then after nine and twenty weeks, participants in both groups complete a number of questionnaires to measure psychological distress and to find out if they have experienced any further intimate partner violence.

What are the possible benefits and risks of participating?
Participants who take part in the Nguvu program may benefit from reduced levels of distress and intimate partner violence. Participants who receive the standard care services are also likely to benefit in this way should they choose to use the services that are available. The main risks of this study involve possible discomfort when discussing personal topics related to mental health and intimate partner violence and social/safety risks if the participant's partner or other community members are aware of their participation.

Where is the study run from?
The study is run from the Muhimbili University of Health and Allied Sciences and takes place in the Nyarugusu Refugee Camp (Tanzania)

When is the study starting and how long is it expected to run for?
October 2014 to October 2017

Who is funding the study?
1. Wellcome Trust (UK) Reference: R2HC initiative
2. Department for International Development (UK)

Who is the main contact?
1. Miss M Claire Greene (public)
2. Mr Wietse A Tol (scientific)

Previous plain English summary:
Background and study aims
Intimate partner violence is a major concern in refugee camps, as well as putting people at risk of mental health issues such as anxiety and depression (psychological distress). Studies have shown that psychological distress and intimate partner violence are directly related, in that intimate partner violence causes worse mental health and in turn mental health issues can increase risk of further intimate partner violence. It can be very difficult to break this cycle, and so an approach that addresses both mental health and the violence is necessary (integrated approach). The Nguvu (Kiswahili for strength and energy) project is an integrated approach designed to address these issues, through a combination of empowerment (providing information, discussing options and helping women make safe and informed choices to reduce violence) and psychological support (reducing emotional difficulties resulting from violence exposure). The aim of this study is to investigate the effectiveness of this program at reducing psychological distress and preventing future intimate partner violence.

Who can participate?
Women who are refugees from the Democratic Republic of the Congo (DRC) currently living in

Nyarugusu Refugee Camp (Tanzania) and participating in local women's groups who have a history of intimate partner violence and are experiencing psychological distress.

What does the study involve?
The Nyarugusu Refugee Camp is divided into seven zones for Congolese refugees, which are further subdivided into 52 villages. Local women's groups are organized within these villages and operate as opportunities for women to develop skills and strengthen their social networks. There are 59 women's groups located in zones two through seven, which are randomly allocated into one of two study conditions: usual care with and without Nguvu. Participants recruited from women's groups in the first group take part in the Nguvu program. Women's groups in zone one are not included in the trial as this served as the sampling frame for our recently completed pilot study. The Nguvu program involves weekly sessions over eight weeks. Sessions one and eight focus on developing a safety plan and discussing issues surrounding intimate partner violence and psychological distress. Sessions two-seven focus on learning techniques to help identify stuck thoughts and learn skills to change ways of thinking that lead to psychological distress. Those living in villages in the usual care condition receive access to standard mental health and protection services during the eight week study period. This includes gender-based violence prevention and response services provided by the International Rescue Committee in Nyarugusu camp and mental health services provided by the Tanzania Red Cross. At the start of the study and then after nine and twenty weeks, participants in both groups complete a number of questionnaires to measure psychological distress and to find out if they have experienced any further intimate partner violence.

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Contact information

Type(s)
Public

Contact name
Miss M. Claire Greene

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Type(s)
Scientific

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624 North Broadway, Rm. 863
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United States of America
21205

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N/A

Study information

Scientific Title
Nguvu: A randomized controlled trial of an integrated intervention to reduce intimate partner violence and psychological distress in adult, female Congolese refugees in Tanzania

Study objectives

Study hypothesis as of 07/11/2018:
To assess the relevance, acceptability and feasibility of a future definitive randomized controlled trial (RCT) evaluating the efficacy of an integrated intervention to reduce psychological distress and intimate partner violence for adult refugee women

Previous study hypothesis:
1. Women in the intervention condition (consisting of the 8-session Nguvu intervention and access to intervention as usual) will report fewer incidents of intimate partner violence and experience less psychological distress post-intervention relative to intervention as usual
2. The intervention will increase social support/capital, self-efficacy and adaptive coping skills, which will further reduce recurrent intimate partner violence and psychological distress

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Johns Hopkins Bloomberg School of Public Health, 20/09/2016, ref: 00007219
2. Muhimbili University of Health and Allied Sciences, Tanzania, 20/10/2015, ref: 2014-10-27/AEC /Vol.X/56
3. National Institute of Medical Research, Tanzania, 11/09/2015 ref: NIMR/HQ/R.8a/Vol.1X/2016

Study design
Study design as of 31/10/2018:
Single-centre randomized pilot controlled trial

Previous study design:
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
cluster randomized pilot trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Psychological distress (e.g. depressive, anxiety or post-traumatic stress symptoms) in refugees with a past-year history of intimate partner violence

Interventions
Correct as of 12/06/2017:
Nyarugusu is divided into 7 zones for Congolese refugees, which are further subdivided into 52 total villages.

One of the zones (zone 1) will be excluded from the trial because it was used as the site for the pilot study. In zones 2-7 there are 59 women's groups organized within the villages, which will serve as the cluster and source of recruitment for the study.

Staff not working for the project at Johns Hopkins Bloomberg School of Public Health will randomize women's groups in zones 2-7 into the intervention and control condition using approximately a 1:1 allocation ratio through a random number generator in the Stata. The allocation of villages to intervention and control condition will be concealed from the local research assistants.

Intervention (Nguvu) Arm: Participants will have access to the Nguvu intervention, which is an 8-week program that integrates advocacy and empowerment counseling with cognitive processing therapy. The intervention was developed from previous programs evaluated in survivors of sexual and gender-based violence and adapted through formative research conducted in Nyarugusu refugee camp. The intervention consists of weekly sessions over the course of 8 weeks (1 individual session followed by 7 group sessions). Sessions 1 and 8 are the advocacy sessions, which focus on developing a safety plan and discussing issues surrounding intimate partner violence and psychological distress. Sessions 2-7 are the cognitive processing therapy sessions that introduce concepts and the relationship between thoughts and feelings and teach participants skills to identify stuck thoughts and introduce skills to change thinking errors as a means to improve feelings and reduce psychological stress.

Comparison group: Participants will receive standard mental health and protection services during the trial period. Protection services include gender-based violence prevention and response services provided by the International Rescue Committee in Nyarugusu camp. The mental health services are provided primarily through the health sector, primarily provided by the Tanzania Red Cross, and some psychosocial services are offered through the protection sector.

Participants in both groups are followed up after 9 and 20 weeks.

Intervention Type
Behavioural

Primary outcome measure
Primary outcome measures as of 07/11/2018:
1. Relevance of the intervention and research protocols
1.1. To determine whether psychological distress is a prevalent problem that is prioritized by women affected by intimate partner violence in refugee settings
1.2. To evaluate the validity and reliability of mental health, violence and functioning outcome measures in the study population
2. Acceptability of the intervention and research protocols
2.1. Participant retention in intervention sessions and research interviews (75% of intervention sessions attended, on average; 85% retention in post-treatment assessment)
2.2. No serious adverse events related to study participation
2.3. Safety and ethical concerns reported in qualitative interviews with participants and program staff
3. Feasibility of the intervention and research protocols
3.1. Fidelity of intervention implementation as determined through supervision, qualitative interviews with intervention facilitators and routine monitoring for protocol deviations
3.2. Recruitment of 15 groups of eligible women (approximately n=150-180) and approximately

equal number of controls within 3 months
3.3. Balanced randomization groups on demographics and baseline levels of outcome measures
3.4. Implementation challenges reported in qualitative interviews with program staff and partner agency representatives, changes in anticipated timelines, etc.
3.5. Monitoring of research protocol deviations to inform adaptations to recruitment, randomization, assessment, and follow-up procedures

Previous primary outcome measures:
1. Recurrence of intimate partner violence is measured using the Domestic Violence Module of the Demographic and Health Survey at baseline, 9 and 20 weeks post-enrollment
2. Psychological distress symptoms are measured using the 25-item Hopkins Symptom Checklist (HSCL-25) and PTSD Symptom Items in the Harvard Trauma Questionnaire (HTQ) at baseline, 9 and 20 weeks post-enrollment

Secondary outcome measures
Secondary outcome measures as of 07/11/2018:
1. Recurrence of intimate partner violence as measured using the Domestic Violence Module of the Demographic and Health Survey at baseline and post-treatment assessments
2. Psychological distress symptoms as measured using the 25-item Hopkins Symptom Checklist (HSCL-25) and PTSD symptom items in the Harvard Trauma Questionnaire at baseline and post-treatment assessments
3. Functional impairment as measured using 12 items developed from qualitative data at baseline and post-treatment assessments

Previous secondary outcome measures:
Functional impairment measured using 12 items developed from qualitative data at baseline, 9 and 20 weeks post-enrollment

Overall study start date
01/10/2014

Completion date
01/10/2017

Eligibility

Key inclusion criteria
Inclusion criteria as of 29/03/2017:
1. Aged 18 years and over
2. Female
3. Refugee from the Democratic Republic of the Congo (DRC) currently residing in Nyarugusu Refugee Camp, Tanzania
4. Participating in a local women's groups
5. Past-years history of intimate partner violence: endorsing any past-year intimate partner violence on a modified version of the Abuse Assessment Screen (AAS)
6. Experiencing moderate-severe psychological distress: Average score of moderate to severe (≥1.75 out of 4) on items assessing depressive or anxiety symptoms; or ≥ 1.0 out of 3 on items assessing post-traumatic stress symptoms. Depressive and anxiety symptoms were measured using the 25-item Hopkins Symptom Checklist (HSCL). Post-traumatic stress symptoms were measured using the 16-item Harvard Trauma Questionnaire (HTQ)

Original inclusion criteria 4-5:
4. Past-years history of intimate partner violence: endorsing any past-year intimate partner violence on a modified version of the Abuse Assessment Screen (AAS)
5. Experiencing moderate-severe psychological distress: Average score of moderate to severe (>1.75 out of 4) on items assessing depressive, anxiety or post-traumatic stress symptoms. Depressive and anxiety symptoms were measured using the 25-item Hopkins Symptom Checklist (HSCL). Post-traumatic stress symptoms were measured using the 16-item Harvard Trauma Questionnaire (HTQ).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
400311

Total final enrolment
311

Key exclusion criteria
1. Serious mental illness
2. Substance use disorder
3. Imminent risk of suicide

Date of first enrolment
03/04/2017

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
Tanzania

Study participating centre
Muhimbili University of Health and Allied Sciences (MUHAS)
United Nations Road
Dar es Salaam
Tanzania
N/A

Sponsor information

Organisation
Johns Hopkins Bloomberg School of Public Health

Sponsor details
615 North Wolfe Street
Baltimore
United States of America
21205

Sponsor type
University/education

Website
www.jhsph.edu

ROR
https://ror.org/00za53h95

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of study results in a high impact journal within 1 year from the trial end date.

Intention to publish date
30/09/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the Principal Investigator, Wietse Tol (wtol1@jhu.edu).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		18/05/2017	22/05/2017	Yes	No
Basic results		27/04/2019	01/05/2019	No	No
Results article		18/06/2021	21/06/2021	Yes	No
Results article		17/08/2019	10/07/2023	Yes	No