ISRCTN17319820 https://doi.org/10.1186/ISRCTN17319820

E le Saua le Alofa (Love Shouldn’t Hurt) 'Proof of Concept' pilot intervention

Submission date
05/03/2024

Recruitment status
No longer recruiting

Registration date
14/03/2024

Overall study status
Completed

Last Edited
11/03/2024

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Violence against women and girls (VAWG) has severe implications for physical and mental health. In the world’s highest prevalence settings, nearly 50 percent of women will experience physical and/or sexual violence from an intimate partner in their lifetime, with the Pacific region having among the highest rates anywhere is the world (Sardinha et al., 2022). In the Pacific Island of Samoa, 39.9% of ever-partnered women have experienced physical, sexual and/or emotional violence in their lifetime and 32.6% in the last 12 months (DHS-MICS 2019-20).

This protocol describes a pre-experimental pilot of an intervention co-developed by 30 village representatives and community members in partnership with the Samoa Victim Support Group, the National University of Samoa, the Samoa Bureau of Statistics and University College London (UCL) as part of the EVE Study (Evidence for Violence prevention in the Extreme). The project is referred to locally as E le Saua le Alofa (Love Shouldn’t Hurt).

The aim of the pilot is to provide a ‘proof of concept’ of using the E le Saua le Alofa intervention, and specifically its participatory, co-developed approach, to prevent VAWG in Samoan communities, with the following objectives/ sub-objectives:
1. To assess whether involving communities in the intervention design process leads to their engagement in VAWG prevention activities;
To assess to what extent village representatives were committed to preventing VAWG in their community;
-- To identify enablers and barriers to engagement (e.g. attendance, levels of participation) of community representatives in intervention activities;
-- To assess retention, adherence, and reasons for drop-out of community members in intervention activities;
-- To identify activities or changes that have arisen in the community as a result of the intervention.
2. To assess the acceptability and feasibility of conducting a definitive randomised controlled trial to measure the effectiveness of the intervention in reducing VAWG outcomes;
-- To refine calculations of sample size for a definitive cluster randomised controlled trial;
-- To assess the feasibility of conducting a survey using self-completion skip-logic questionnaires delivered on mobile phones/ tablets;

-- To understand social norms and practices that may have implications for randomisation of clusters, recruitment, questionnaire protocols, and participatory analysis.

Who can participate?
Adults aged 18 and above who are residents of participating villages.

What does the study involve?
The study is a pre-experimental pilot evaluation of an intervention designed to prevent VAWG in Samoan villages. Ten villages have been purposively selected to participate in the pilot study based on obtaining a diversity of size, location, and reported rates of VAWG. Three village representatives from each village (1 man, 1 woman, 1 elder; n=30) will attend a workshop in Apia (the capital city) where the participatory activities will be tested, refined and adapted. Activities have been pre-selected from evidence-based interventions from around the world to fit with a theory of change developed by the village representatives at an earlier stage of the project (see Mannell et al. 2023). 30 residents from each of the 10 villages (n=300) will then be invited to participate in 6x1-day workshops delivered over a 6-month period. The evaluation of the pilot study includes a quantitative survey questionnaire delivered to the village representatives and all participants before and after the intervention period, the collection of 'stories of change' in participating villages, intervention workbooks completed by the village representatives, interviews with village representatives, and detailed notes from community conversations at the end of the intervention.

What are the possible benefits and risks of participating?
Benefits of participating include receiving an intervention to prevent VAWG in communities developed for Samoa and involving Samoan village representatives in its delivery. This is expected to increase community ownership, relevance of intervention activities, sustainability of changes through effective community leadership, and reduce harmful gender norms that drive VAWG. Risks of participating include the potential for conflict in villages arising from efforts by village representatives to challenge widely held social norms about the use of VAWG in some situations as a means of controlling women’s activities. These risks will be closely monitored during the pilot evaluation using both quantitative and qualitative (observational) data, and the pilot will be stopped if it is decided that the risks outweigh the benefits of the intervention.

Where is the study run from?
The pilot intervention will be run by the Samoa Victim Support Group (SVSG). The before and after intervention survey data will be collected by the project team in close collaboration with the Samoan Bureau of Statistics and the National University of Samoa.

When is the study starting and how long is it expected to run for?
The pilot intervention will start on the 1st July 2023 and run for 6 months. The survey data will be collected in June 2023 for baseline and February 2024 for endline.

Who is funding the study?
The study is funded by UKRI (grant MR/S033629/1).

Who is the main contact?
Professor Jenevieve Mannell; j.mannell@ucl.ac.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

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Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Participatory Community-led Intervention Development (PCID) Pilot: Assessing the acceptability and feasibility of a co-produced intervention to prevent violence against women in Samoa

Acronym
PCID

Study objectives
The intervention will (1) engage community members in violence against women prevention activities, and (2) be acceptable and feasible for Samoan communities

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/05/2020, University College London - Research Ethics Committee (30 Guilford Street, London, WC1N 1EH, United Kingdom; +442076792000; ethics@ucl.ac.uk), ref: 9663/002

Study design
Single-centre pre-experimental 'proof of concept' study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Women or gender diverse individuals experiencing violence from a male perpetrator

Interventions
The intervention consists of 6 x 1-day participatory workshop sessions covering topics including: Power and Inequalities; Healthy relationships; Self-reflection on communication and risky behaviours; Positive Parenting; Livelihoods; and Supporting Survivors. Each topic has been chosen from a theory of change co-developed by the village representatives at an earlier stage of the project.
The total duration of intervention and follow-up is 11 months.

Intervention Type
Behavioural

Primary outcome(s)
1. Community engagement in VAWG prevention activities, measured at 8-12 weeks after the end of the intervention (at 44-48 weeks after the start of the intervention) using
1.1. 'Stories of change' from participating communities
1.2. Intervention workbooks
1.3. Interviews with village representatives
1.4. Interviews with community members
1.5. Observational fieldnotes
2. Acceptability and feasibility of a definitive trial of the intervention:
2.1. Intervention workbooks at 8-12 weeks after the end of the intervention (at 44-48 weeks)
2.2. Interviews with village representatives at 8-12 weeks after the end of the intervention (at 44-48 weeks)
2.3. Survey estimated prevalence of secondary outcomes at Baseline and 8-12 weeks after the end of the intervention (at 44-48 weeks)
2.4. Survey estimated intra-cluster correlation (ICC) of survey data at Baseline and 8-12 weeks after the end of the intervention (at 44-48 weeks)

Key secondary outcome(s))
Measured at Baseline and 8-12 weeks after the end of the intervention (at 44-48 weeks):
1. Past 6-month frequency of experience of physical/ sexual/ emotional/ economic violence among women from an intimate partner measured using Demographic and Health Survey (DHS)-Multiple Indicator Cluster Surveys (MICS) domestic violence module
2. Lifetime experience of physical/ sexual/ emotional / economic intimate partner violence by women measured using DHS-MICS domestic violence module
3. Frequency of men's past perpetration of physical/ sexual/ emotional/ economic violence against an intimate partner in the past 6 months measured using United Nations Multi-country Study on Men and Violence
4. Frequency of men's past perpetration of physical/ sexual/ emotional/ economic violence against an intimate partner in their lifetime measured using United Nations Multi-country Study on Men and Violence

5. Lifetime experience of physical/ sexual non-partner violence among women measured using DHS-MICS domestic violence module
6. Witnessing parental violence measured using Witnessing parental violence (World Health Organisation (WHO) Multi-country study on Women's Health and Violence)
7. Experience of physical child abuse measured using Childhood experiences of violence (EASE-PI)
8. Gender views and injunctive social norms about violence measured using Gender Equity Scale (GEM)
9. Depression measured using Self-report depression (CES-D)
10. Harmful drinking behaviours measured using Alcohol Use Disorder Identification Test (AUDIT)
11. Generalised anxiety disorder measured using Generalised Anxiety Disorder (GAD-7)

Completion date
31/03/2024

Eligibility

Key inclusion criteria
1. Resident of participating villages
2. Age: 18 years or older

Participant type(s)
Resident

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
300

Key exclusion criteria
1. Individuals experiencing active and unmanaged psychosis,
2. Unable to provide informed consent
3. Not living permanently in participating villages
4. Under the age of 18 years
5. Living in households where appropriate safety measures cannot be ensured

Date of first enrolment

01/05/2023

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Samoa

Study participating centre
Samoa Victim Support Group
Apia
Samoa
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Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated during and/or analysed during the current study will be stored in a publicly available repository at a later date (within 3 years of the completion of the project) at: https://www.ucl.ac.uk/library/open-science-research-support/research-data-management/ucl-research-data-repository

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes