



WOREC



12th National Summit of Health and Population Scientists in Nepal

Ensuring Ethical Conduct and Safeguarding Participants' Safety in a Randomized Controlled Trial of a Multi-component Family Intervention for Intimate Partner Violence and Depression in Nepal

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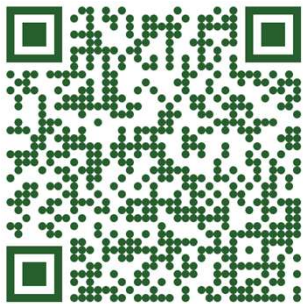


- Health service researcher with extensive training & experience in conducting impact evaluation & implementation research, using mixed-method approaches.
- Education:
 - Postdoctoral training, University of Houston College of Pharmacy
 - PhD in Health Services & Policy, University of Iowa College of Public Health

RATIONALE

- Intimate Partner Violence (IPV) & depression are interrelated, affecting 25-50% of women in South Asia.(Satyanarayana et al., 2015; Chandra et al., 2009)
- About 27% of women experience IPV in Nepal.(Sapkota *et al.*, 2024)

Behind the Seen: Searching for Peace in a House With Violence



Supporting women who cannot leave an abusive relationship



Pilot testing of family-based intervention



SUMMARY OF MILAP TRIAL

Study Title: A randomized controlled trial of a Multi-component family Intervention to Lower depression & Address intimate Partner violence (MILAP) among young women in Nepal

Collaborators: Possible, University of California San Francisco (UCSF), Wheaton College, Women's Rehabilitation Centre (WOREC) Nepal

Multi Principal Investigator(s): Bibhav Acharya & Sabitri Sapkota

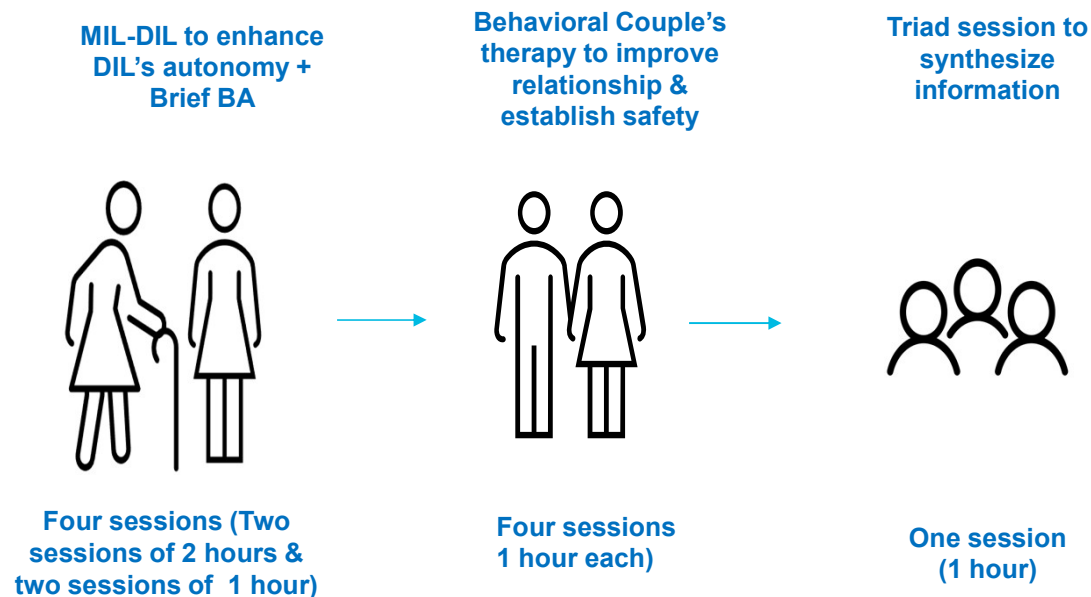
Study Timeline: June 1, 2024 – March 31, 2029

- Conduct a 12-month randomized controlled trial (RCT) to assess the effectiveness of MILAP on depression, intimate partner violence, & PTSD among young married women in Nepal.
- Conduct a mixed-methods assessment of theorized mechanisms of change for MILAP's intervention effectiveness.
- Conduct a cost-effectiveness analysis of MILAP for depression & intimate partner violence.

OBJECTIVE 1: Conduct 12-month RCT

MILAP: Multi-component family Intervention to Lower depression & Address intimate Partner violence (MILAP) among young women in Nepal

- Delivered by trained psychosocial counselors



Enhanced Usual Care (EUC)

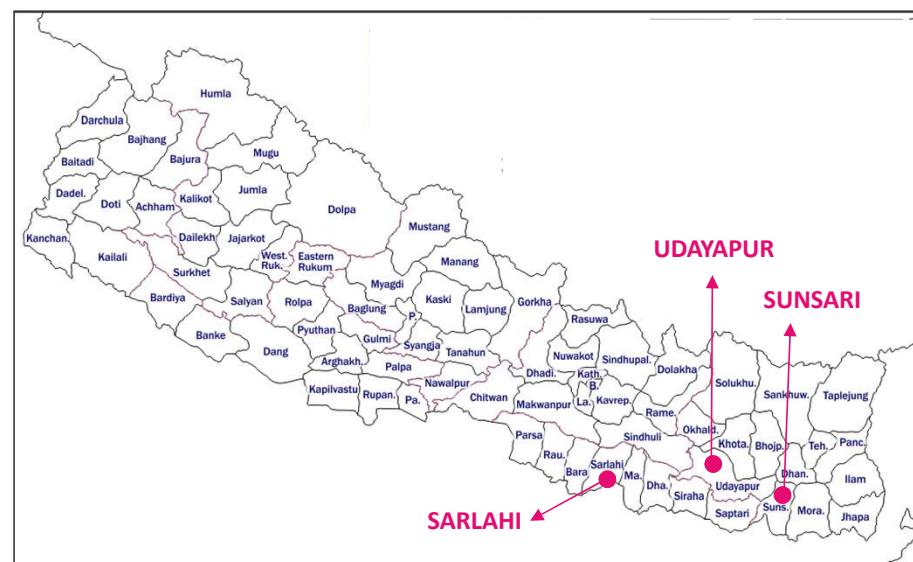
- Usual Care
 - Initial safety assessment
 - Individual & group counseling services based on the participants' needs & decisions
 - Educational materials & IPV referral card
- Enhanced by adding two major services, if indicated
 - **Crisis management**
 - **Referral mechanism**

METHODOLOGY

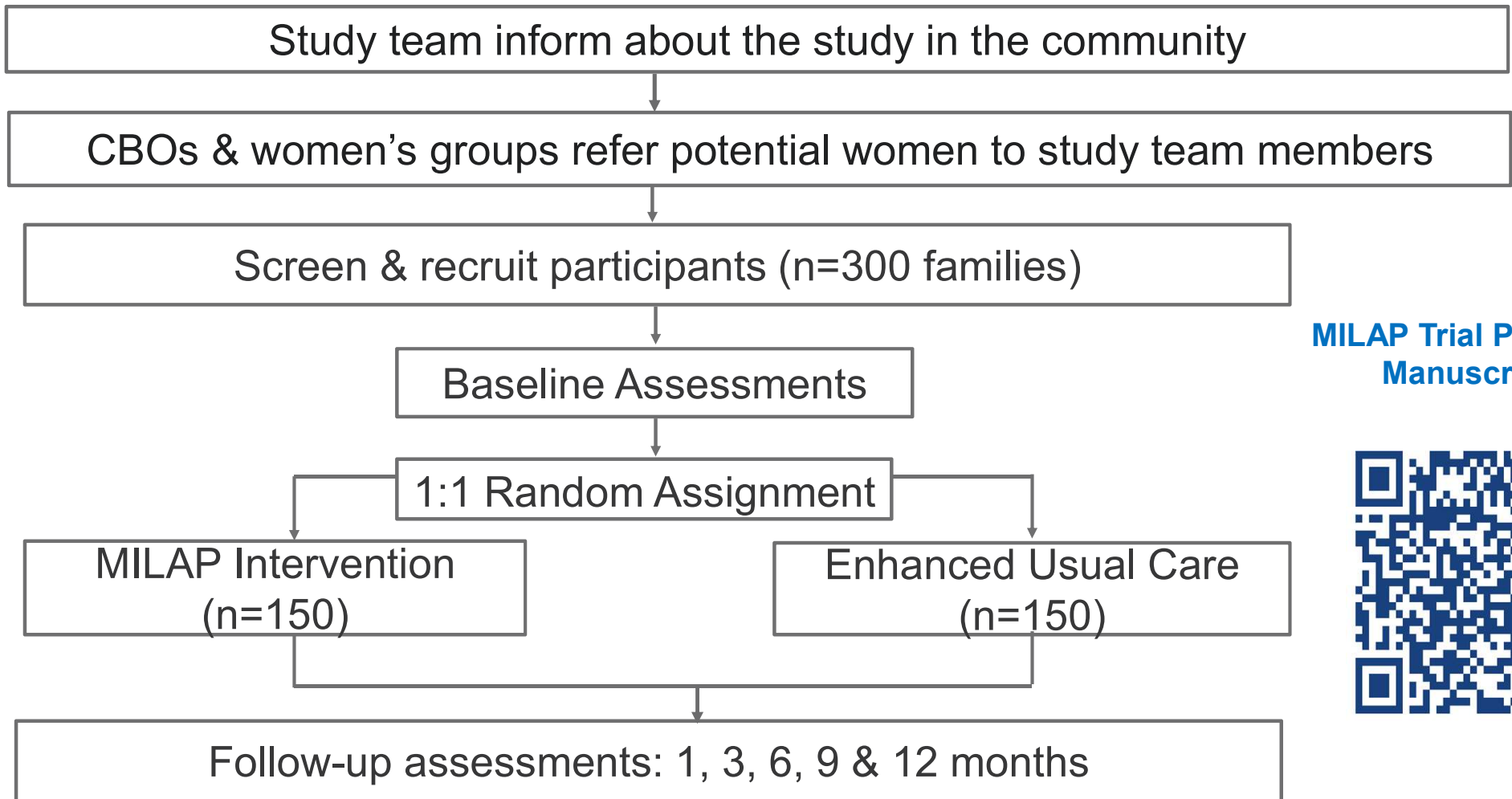
STUDY PARTICIPANTS

1. married women aged 15-24
 - a) reporting IPV (physical violence, sexual violence, or abusive control) in the last 12 months;
 - b) expressing desire to remain in the current relationship/family
2. their husbands, & MILs sharing a household

STUDY SITES



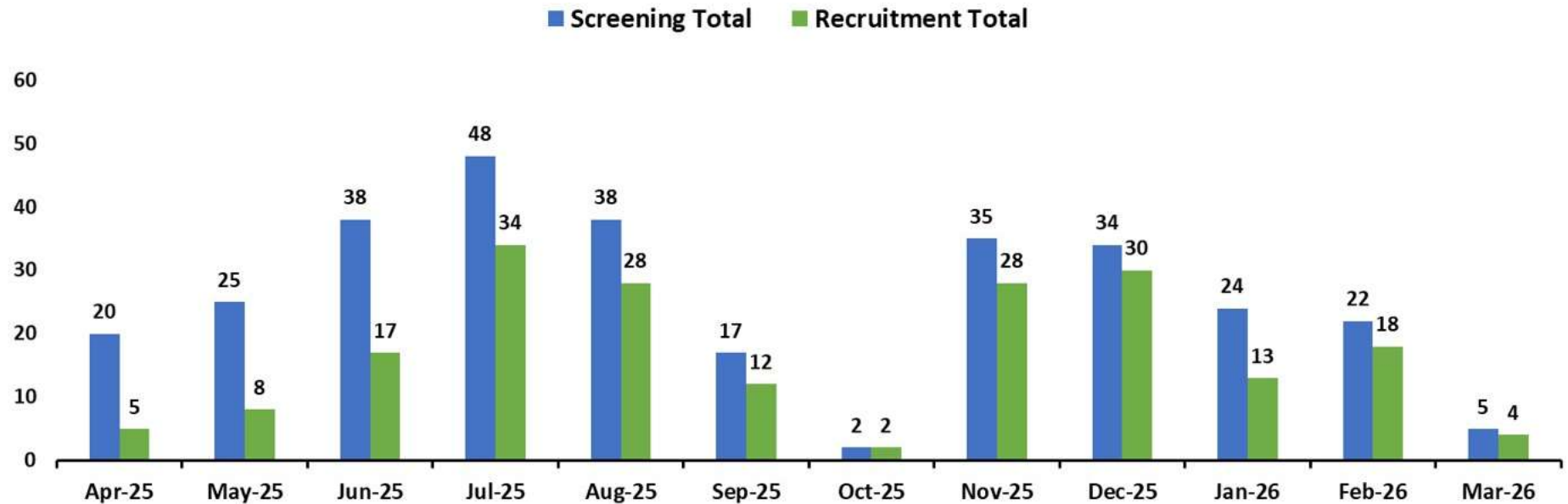
STUDY FLOW OF MILAP RCT



MILAP Trial Protocol
Manuscript



RECRUITMENT UPDATE [As of Mid-March 2026]



- Total Recruited: **199 Triads** out of 300 Study Sample
- Total Reported Adverse Events: 40
 - 36 non-serious & 4 serious
 - all unrelated to study participation

PRESENTATION FOCUS

- How to build ethical safeguarding as a dynamic system of protection embedded throughout the entire trial design, and rather than just as a procedural checkpoint?

WHY ETHICS IS CENTRAL IN IPV AND FAMILY-BASED INTERVENTION TRIALS?

- IPV is hidden, stigmatized, ongoing, and relationally embedded
 - Communication challenge, privacy and confidentiality, recruitment
- Family intervention
 - Risk is not external, but inside the unit of study
- Involvement of Husband and Mother-in-law
 - Power hierarchy inside the trial
- Depression + IPV
 - Heightened vulnerability + Safety sensitivity
- Safety and emotional burden to the research staff

MAPPING ETHICAL RISKS (1)

LEVELS	DOMAINS	ETHICAL CONCERNS
Individual Level (IL)	Women's autonomy	Women participants' autonomy in making decision about study participation and assessment
	Privacy	How to ensure privacy of information shared?
	Safety and vulnerability	Direct harm such as psychological distress due to disclosure of IPV and depression
Household Level (HL)	Embedded violence and safety risk	Stigma, conflict and retaliation post-intervention and assessment
	Power dynamics	Influence of family members - Intervention & Assessment
	Recruitment	How do you recruit husband and MIL participants?

MAPPING ETHICAL RISKS (2)

LEVELS	DOMAINS	ETHICAL CONCERNS
System Level (SL)	Participants' safety	How do you ensure safety of all participants, including ineligible participants?
	Adverse event monitoring	How do you identify, report and manage any adverse event, especially in EUC arm?
	Crisis management	What do you do when participants express suicidal ideation/attempt?
	Safety and emotional burden of field staff	How do you ensure team members' safety & well-being?
	Researchers' positionality	How do you prepare your team members for this trial?
	Referral pathways	Connecting participants in need of different level of services?
	Institutional governance	How do you built-in governance requirements within the trial process?

RISK MITIGATION (1)

IPV and Depression related Stigma

- Presenting MILAP study as skills-enhancement program to improve family relationships; Study details during consenting
- Sensitization training of team members

Women's autonomy and Privacy (IL & HL)

- Tiered communication & consenting
- Women's decision about whether & how to communicate with their husbands & MILs
- Safe & private location
- Limited interaction by designated RA & counselor

Power Dynamics (HL)

- Independent and confidential consenting
- Individual assessment sessions
- Inclusive & participatory intervention sessions



RISK MITIGATION (2)

Recruitment (IL and HL)

- Establishing trust, ensuring confidentiality, & reiterating their right & option to decline to answer
- Flexibility of time and location
- Collaboration with community-trusted CBOs



Safety and Vulnerability (at all levels)

- Non-blaming communication approach
- Comprehensive safety protocol with clear role clarification
- AE checks at each contact point for participants in both arms
- Regular follow-ups for well-being check
- Resource card to all triad members normalizing seeking help
- Crisis counseling for imminent & high suicidal risk, with follow-up check-ins
- Referral to One-Stop Crisis Management Centers, tertiary care facilities, other clinical & non-clinical services
- Sharing resources with ineligible participants, & well-being check for high risk cases
- Sensitive management of individual drop-outs



RISK MITIGATION (3)

Researchers' positionality

- Local female research team members & counselors communicating in native languages
- Training on practical and contextual strategies, informed by pilot studies
- Coordination with local stakeholders



Research team members' safety

- Regular well-being sessions & supportive supervision
- Clear guideline on how to seek help, report and manage any safety issues



RISK MITIGATION (4)

Methodological Safeguards

- Trial protocol with clear role clarification for each process/step, & detailed guides & scripts
- In-built blinding strategies in trial procedure
- Insights from two pilot studies, & our other RCTs
- Feedbacks from Community Advisory Board & District Coordination Committees
- Expert advice (advisors & independent data safety & monitoring board)

Institutional Governance (regular ethical reviews by ethical review boards, funder & Social Welfare Council)



Ethics Brief



KEY TAKEAWAY MESSAGES

- Ethics is just not an IRB review requirement, this is intervention architect
- Consent is a process, not a signature only
- Family-based interventions require dual-layer safeguarding (woman + household system)
 - Is the woman safe as an individual?
 - Could the intervention shift family dynamics in a way that creates harm?
- EUC arms require equal ethical attention
- Research staff wellbeing is part of ethics

ETHICS MUST BE ADAPTIVE AND ITERATIVE

ACKNOWLEDGEMENTS

- Research participants
- Community advisory boards
- District coordination committees
- University of California San Francisco
- Wheaton College
- Nepal Health Research Council
- National Institute of Mental Health
- Sexual Violence Research Initiatives
- Anonymous donor
- All stakeholders

THANK YOU!

QUESTIONS?