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ClinicalTrials.gov NCT05130632

The problem-globally

Ambient and household air pollution represent the single largest environmental risk factor for ill health, but the contribution of waste burning, specifically open burning of plastic waste, has not been evaluated.





- 2 billion people lack solid waste collection services
- Some studies done on pollutants released from open burning of mixed solid waste
- Lack of studies on hazardous pollutants specific to plastic burning in household fires (indoor and outdoor)

The problem-Guatemala

Household Air Pollution (HAP) is a significant problem in Guatemala where 84% of rural households use solid fuels for cooking --(2019, WHO, Global Health Observatory)

- While clean cookstove programs have focused on the health consequences of HAP in low-resource communities, programs that address waste burning, specifically the <u>open waste burning of</u> <u>plastics</u>, are absent
- 71% of households burn waste as the primary means of disposal (Guatemalan Ministry of Health census, 2018)

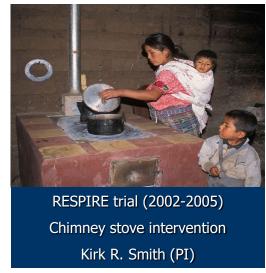






Figure 1 Plastic trash in outside fire (left) and inside kitchen stove (right)



Why is this an equity problem?

- Plastic is derived from petrochemicals; production of single use plastic is growing exponentially
- Plastic waste is a global problem, but problem varies locally based on appropriate waste management
- Marine litter comes from land litter (if it is not burned)
- When burned, plastic produces many atmospheric pollutants, including greenhouse gases, black carbon, reactive trace gases, particulate matter, and toxic compounds, such as polycholorinated and polybrominated dioxins and furans
- Rural and urban poor experience the burden of this problem. In Guatemala, many of these rural communities are indigenous and have been marginalized and discriminated against for centuries.



Wood and plastic fuel indoor cookstove

Study Overview



Evaluate implementation strategies to reduce household-level plastic burning ("THE THING") in rural Guatemalan indigenous communities.

- Advance the adoption, implementation, and sustainability of community-driven actions in intervention villages
- Develop an approach for policy-relevant solutions that combine evidence from effective implementation strategies, exposure assessment, and atmospheric emissions.
- Address environmental and health equity

Specific Aims

- 1. Using dynamic working groups, implement and evaluate strategies that address household level plastic waste burning, targeting barriers and enablers identified within the capability, opportunity, and motivation domains, for key behaviors (guided by Michie's Behavior Change Wheel framework), focusing on assessment of implementation fidelity, reach and potential for scale-up (guided by Glasgow's RE-AIM framework).
- Compare urinary biomarkers of exposure to plastic combustion (bisphenols, phthalates, polycyclic aromatic hydrocarbons and volatile organic compounds) and personal airborne fine particulate matter (PM2.5) and black carbon (BC) in reproductive age women. Hypothesis: Biomarkers and exposures will decrease over time in 200 women from 8 intervention villages compared to 200 women from 8 control villages at 4 and 12 months.
- 3. Using filter-based antimony (Sb) and 1,3,5-Triphenylbenzene (TPB) as tracers of plastic burning and collecting household plastic waste, apportion PM2.5 and quantify emissions estimates of air pollutants from plastic incineration and assess effects of potential emissions reduction on air quality with a chemical transport model.



Aim 1: Implement dynamic working groups In 8 intervention villages

75 persons in each village, n=600; Includes 400 women from Aim 2

Week | Theme



Solid waste management problems

8 intervention villages

Dynamic working group sessions
(3 months) + 9 months

maintenance visits

25 women in each village, n=200

8 control villages

25 women in each village, n=200

Hypothesis: Biomarkers and exposures to plastic burning will decrease in women in intervention villages compared to women in control villages between baseline, 4 and 12 months.

Aim 2: RCT ITT analysis (n=400)



Aim 3: Model emissions from plastic burning on regional scale

quality using a chemical transport model.



Using filter-based tracers of plastic burning, estimate emissions of air pollutants from plastic incineration.
Assess effects of potential emissions reduction on air

PILOT IN
FORMATIVE
PHASE TO
DEVELOP
INTERVENTION
USING COM-B



	ESSENTIAL ELEMENTS			burning, like recycling
		2	Plastic waste practice	Sources of contamination (air, land, food)
		3	Plastics in waterways and oceans	River-ocean flow of plastic; ban in Guatemala
		4	Exposure to burning plastic	Dangers of burning plastics in household fires
		5	Sustainable alternatives to plastic litter	Alternatives to avoid plastic litter
		6	Recycling plastic	Discuss recycling, sorting recyclable materials
		7	Reusing and repurposing plastic	Community clean-up/collecting recyclables
				Ideas and activities reusing/repurposing plastics
	ш	8	Outline potential interventions	Brainstorming projects to reduce plastic burning.
	сиѕтом	9-12	Dynamic group work selects community activities. CAB, stakeholders and external	
			resources develop & support reduced plastic burning by reducing use, reusing or recycling.	
		12-52	Weekly meeting with village champion(s), project fieldworker(s) & stakeholders to support	
	O		activities. Evaluate activities and address bottlenecks to success using RE-AIM .	

Do community working groups reduce plastic waste burning? Target capability, opportunity, and motivation domains for key behaviors guided by Michie's COM-B/TDF framework.

Assess fidelity, reach and potential for scale-up guided by Glasgow's RE-AIM framework.

Components

Plastic use and disposal; Alternatives to plastic

A complex intervention in a low-resource settings: key ingredients

Theories, Models and Frameworks

Interdisciplinarity of team

Stakeholders/community engagement

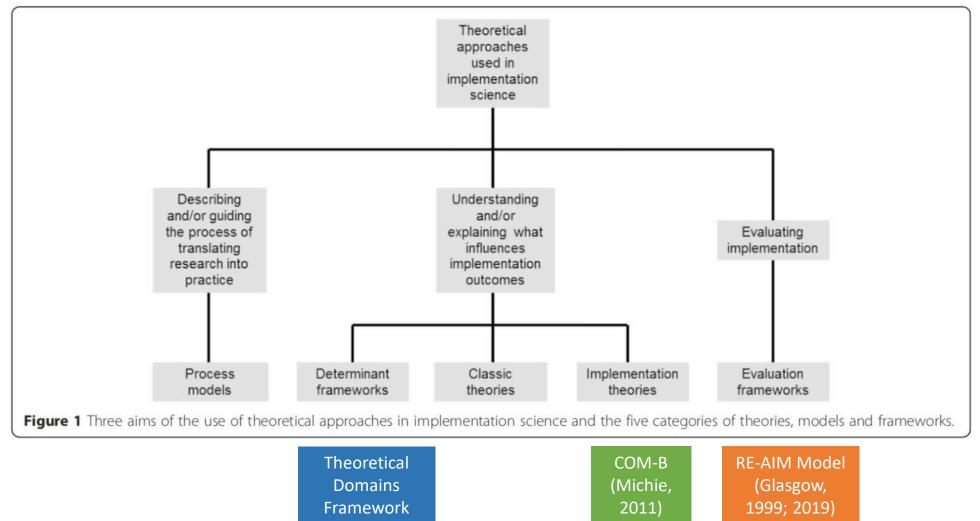
Context "real world"—
needs/resources
assessment

Integrity/standardization of the intervention

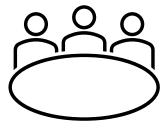
Process evaluation/ supportive feedback mechanism

Hawe, P. (2004); Ramaswamy, R. (2018).

Implementation Science Frameworks Five "frameworks" domains



(Cane, 2012)





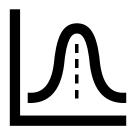








implementation scientists, medical anthropologist, atmospheric chemist, environmental epidemiologist, biostatistician, analytic chemistry, air pollution technicians, laboratory technicians, information technology specialist, teachers, nurse(s) and a graphic designer



Community Engagement

- Permission from indigenous communities of Xalapam (COCODES, community coodinators)
- Present and work with regional and municipal officials and relevant ministries
- Form Community Advisory Board (CAB) with 15 members
- Village champions identified in each community (typically the COCODE)
- Field workers come from these communities



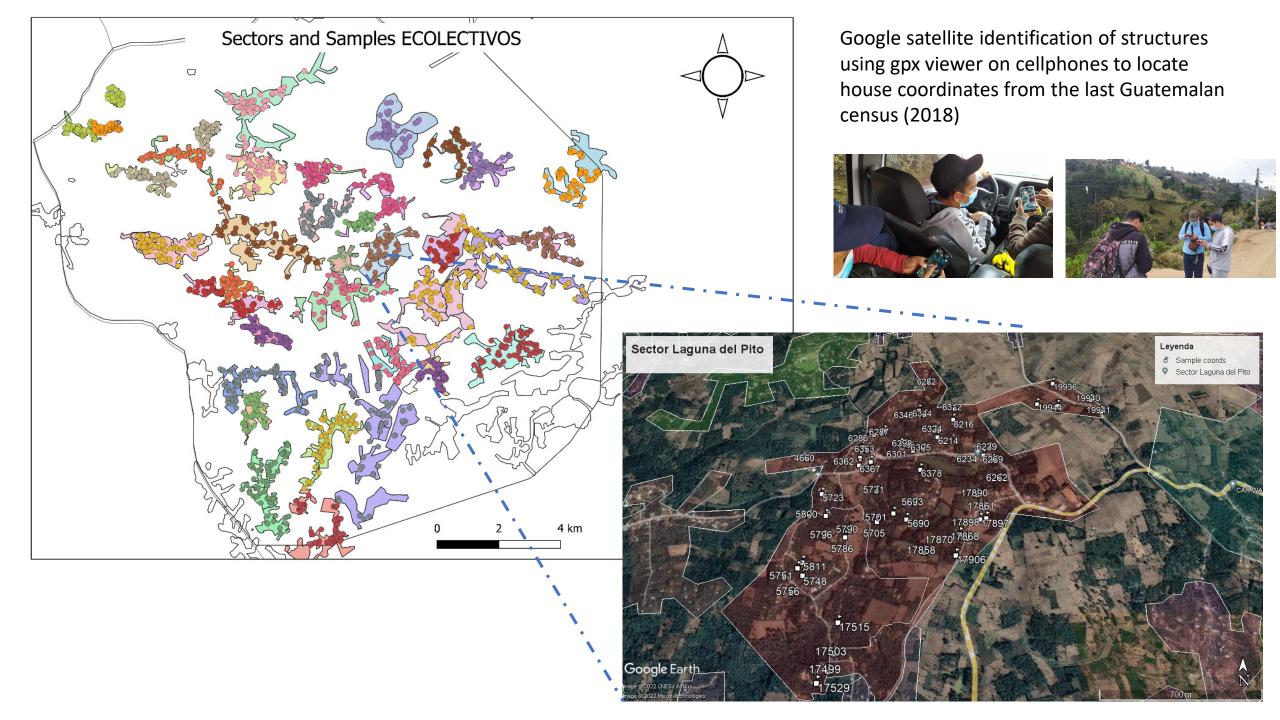


Context "real world" – needs/resources assessment





- Baseline assessment of 1630
 households in 37 Xalapam sectors in
 Jalapa, Guatemala
 - Simple random sampling of 60 households in each sector, oversample to achieve 44 households per sector
 - Assessment of demographics, household energy, waste management, and capabilities, opportunities and motivations to change behaviors that reduce plastic waste burning
 - Identify 400 women of reproductive age (25 from each village) who report burning plastic trash as a primary form of waste disposal at the rapid assessment



Integrity/standardization of the intervention

Refine dynamic working group curriculum

- 10-20 participant observations on waste management practices, including people who burn plastic trash
- 50 open-ended surveys focusing on feasibility and acceptability of capabilities, opportunities and motivations to reduce plastic waste burning
- 10-20 key informant interviews with community stakeholders who recycle, dispose or repurpose plastic trash



Integrity/standardization of the intervention





Pilot and refine essential elements of the dynamic working group curriculum (12 weeks) in one village as a practice run for the Main Trial

Implementation Science in one slide



The intervention/
practice/innovation is
THE THING



Effectiveness research looks at whether THE THING works



Implementation research looks at how best to help people DO THE THING



Implementation strategies are the stuff we do to try to help people DO THE THING



Main implementation outcomes are HOW MUCH (extent) and HOW WELL (quality) they DO THE THING

Dynamic Working Groups, the "Thing"

Eight core modules – the "essential ingredients" and four periphery modules -- that we posit will reduce plastic waste burning – will be implemented.

PILOT IN
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	Week	Theme	Components
	1	Solid waste management problems; sources of plastic contamination	Plastic use and disposal; alternatives to plastic burning, like recycling Activity: Groups discussion concerning waste management and plastic burning as a way of disposal
S	2	Personal, family, and community practices on solid waste management, focus on plastics	Sources of contamination (air, land, food) Activity: Documentaries concerning plastic production, use and disposal/Groups discussions
ESSENTIAL INGREDIENTS FOR ALL VILLAGES	3	Plastics in waterways and oceans Plastics in the ocean, harmful effects on marine life, plastic islands, plastic ban in Guatemala	Activity: Workshop to repurpose plastic materials and fabrication of more environmentally friendly products to avoid plastic use
OR A	4	Contaminants in burning plastic and health implications of exposure	Dangers of burning plastics in household fires Activity: Community compost
DIENTS F	5	Sustainable alternatives to plastic and reducing plastic litter in the community	Activity: community clean-up/collecting of non- recyclable plastics in the community and fabrication od products using these materials
NGREI	6	Recycling plastic	Discuss recycling Activity: sorting recyclable materials
NTIAL IN	7	Reusing and repurposing plastic	Methods of reusing plastics Activity: Making of organic soaps to avoid products that come in plastic packages
ESSE	8	Wrap-up. Formation of groups to outline potential interventions	Group activity: brainstorming community projects to reduce plastic burning.
MIZED	9-12	Dynamic group work to select intervention(s) for the community. Includes bringing in CAB, other stakeholders and external resources to develop and support community intervention(s) that reduce plastic burning by reducing use, reusing or recycling.	
CUSTOMIZED	12-52	Weekly meeting with village champion(s), project fieldworker(s) and stakeholders to support activities that community chooses. Evaluate activities and address bottlenecks to success using RE-AIM .	

Using RE-AIM Implementation Measures at each Plastic Risk Reduction Step

Engagement

with Risk Reduction Behaviors (Behavior Change Activities that Reduce Plastic)
(Step 1)

Adaptation/Implementation

of Risk Reduction Behaviors (Step 2)

Maintenance/Sustainment

of Activities for either original or adapted Risk Reduction behaviors (Step 3)

Reach

Who engages with behavior change activities?

Women: Number, proportion and type of women who come to working groups; #/range/types of behavior changes attempted within intervention group; intensity of change per behavior; assessed at weekly working group sessions Household: Number, proportion and type of

household members engaged?

Village: Who else in village engaged?

Women: Number, proportion and type of women who made adaptations to behaviors they changed; level of change per behavior, assessed at 4 months Household: Number, proportion and type of household members who adapted behaviors?

Village: Who else in village adapted

behaviors?

Women: Number, proportion and type of women who maintained any adaptation 1+ behavior; level of sustained activity per behavior, assessed at 12 months

Household: Number, proportion and type of household members who maintained behaviors?

Village: Who else in village maintained behaviors?

Effectiveness

Did the level of behavior (high/low) effect health outcomes? Women: Total change across behaviors (effectiveness); What is the effect of the behavior changes on collective efficacy? General self efficacy? Health-related quality of life? urinary biomarkers of exposure (e.g., bisphenols, phthalates, polycyclic aromatic hydrocarbons, and volatile organic compounds)? Collect at baseline

Women: Total change across behaviors (effectiveness); What is the effect of the behavior changes on collective efficacy? General self efficacy? Health-related quality of life? urinary biomarkers of exposure (e.g., bisphenols, phthalates, polycyclic aromatic hydrocarbons, and volatile organic compounds)? Compare baseline to 4 months

Women: Total change across behaviors (effectiveness); What is the effect of the behavior changes on collective efficacy? General self efficacy? Health-related quality of life? urinary biomarkers of exposure (e.g., bisphenols, phthalates, polycyclic aromatic hydrocarbons, and volatile organic compounds)? Compare baseline to 12 months

Adoption*

Did participating household and village members complete behavior change activities?

For each participating household/village:

level of change per behavior and range of behaviors within households and intervention village.

For each participating

household/village: range of behaviors that were adapted within households and intervention villages who engaged and at what level?

For each participating

household/village: range of behaviors that were maintained within households and intervention villages who engaged and at what level?

^{*}Assess barriers/enablers to adoption and sustainment with original and/or adaptation of behavior changes



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