

Plastic Waste and Human Health Effects in Guatemala (Ecolectivos)

NCT05130632

Date: April 21, 2024

STUDY00002412

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 800 people that will be a part of the study in Guatemala, where this study will take place. Half of the people in this study will be asked to do some activities that are different than what the other half will do. This will be decided by chance - the study team does not decide. Having two groups with different activities helps us better understand the best ways to reduce plastic use and burning.

Why is this study being done?

This study is being done to answer the question: *Can we reduce the use of plastics and burning of plastics in household fires in rural Jalapa, Guatemala?* You are being asked to be in this research study because you are an adult over 18 and live in one of the areas of Xalapam in the Department of Jalapa included in this study.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate in home visits to understand about plastic use and plastic burning in your home. The researchers may ask you to do the following 3 times: answer questions about your exposure to smoke, collect urine samples in the privacy of your home, wear a small monitoring device that measures your exposure to smoke, and collect all the trash that your family normally produces over 1 week. We may ask you to wear a silicone wristband, at 2 different times for 8 days, which measures your exposure to chemicals that come from smoke. We may also ask you to attend 12 working group meetings (1-2 hours each weekly meeting) with other people in your village to discuss ways to reduce air pollution and keep your village free of plastic. You may be asked to be a community health promotor. You will be asked to participate in the study for 1 year. All of these activities will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. The results will help us learn more about the smoke problems generated by burning plastic in your

village, which will help plan future research. If your village is selected to participate in working groups, we will offer you a small gift. If you attend the working group sessions, your name will be entered in a raffle for a larger gift.

What are the risks or discomforts I should know about before making a decision?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include loss of privacy and breach of confidentiality. A full list of expected risks, their frequency and severity are in the “Risks and discomforts” section of this document.

Alternatives to Joining This Study

You may choose not to participate.

Costs

You will not have to pay for any of the study activities.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study staff explains the study to you. Feel free to ask questions, for instance about your time commitment, about unfamiliar words, more details on specific procedures. Take time to consider this, and talk about it with your family and friends.

Emory University and Universidad del Valle de Guatemala Consent to be a Research Subject

Title: Estimation of exposure to plastic burning in rural households in Jalapa, Guatemala (ECOLECTIVOS)

IRB #: 245-05-2021

Principal Investigators: [REDACTED], PhD, RN, FNP, Professor, and [REDACTED], PhD, MPA, Associate Professor, Emory University, Atlanta, Georgia

Local Principal Investigator: [REDACTED], MSc, Program Director, Universidad del Valle de Guatemala, Guatemala City, Guatemala

Funding Source: National Institutes of Health of the United States

Introduction

Hello, I am _____ and I work for the Universidad del Valle de Guatemala. I would like to ask you to be in a research study we are doing together with investigators at Emory University in Atlanta, Georgia. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form, you will not give up any legal rights.

Study Overview

This study is being carried out in 16 rural villages in Jalapa, Guatemala. The purpose of this study is to explore options to reduce plastics in the village and reduce the burning of plastics. Smoke from burning plastic can be a health risk for those who breathe it for many months and years. We are interested in knowing the ideas and practices that people in the village have about plastic management. This study will last for 5 years, from 2021 to 2026. However, your participation will last for up to a year.

Your village will be randomized to one of two groups. One group of 8 villages, the 'intervention' group, will be assigned to attend educational working groups about managing plastic waste. The other group of 8 villages, the 'control' group, will not attend working groups. Neither you nor the researcher can choose which group your village will be in. Each participating village has an equal chance of being in either group. We need to have villages in different groups so we can compare whether plastic management is impacted by the working groups. If you choose to participate in this study, and your village is selected to receive educational working groups, we will ask you to participate in these working groups.

There are 5 parts to this study, and it is possible to participate in only 1 or all 5 parts. We describe the 5 parts below.

Part 1: Participate in rapid community assessment

In this part of the study, we will invite people in each village to take part in an interview about their community.

What will happen if you decide to participate in this part of the study?

Interview: We will ask questions about who the leaders are in your community, what organizations work in your community, and how the people in your community work on development projects. Each interview will take 60 – 90 minutes.

How many people will participate in this part of the study? We will interview some people from each community.

Do you have any questions? Are you interested in participating?

Part 2: Collect urine samples and wear a personal monitoring device to measure your body's exposure to smoke.

In this part of the study, we will visit you in your home three times, at the start of study, at about 4-6 months, and at about 12-13 months after the start of the study. We will take a sample of your urine to measure your exposure to smoke. We will also measure your personal exposure to smoke using a small device that measures smoke. This will help understand your exposure to products released from smoke, which are generated by burning plastics.

What will happen if you decide to participate in this part of the study?

Questionnaires: We will ask questions about you and your family, such as age, sex, educational level, occupation, type of stove, and fuels used in your home. We will also ask you about waste/garbage practices in your home, such as when/where you burn waste and your experience and opinions on community activities. In addition, we will ask about your exposures to tobacco smoke, other sources of smoke in your home, and the types of food you ate and the types of personal products you used. This survey will take about 45 minutes.

Urine samples: We will ask you to collect urine samples in the privacy of your home. We will ask that these samples be collected first thing in the morning after you wake up. In addition, we will ask you to write down the time that you took the sample. We will give you a collection cup and a cooler for storing your cup until study staff can collect it from you.

Air pollution monitoring: We will ask you to wear a small personal device that monitors your exposure to smoke in the air for 24 hours. We will also ask for permission to leave another device in the kitchen of your home. Study staff will then measure the amount of smoke you were exposed to over this time period. We will visit your house on the first day to place the monitors and return the second day to pick up the monitors when we pick up the urine sample.

How many people will participate in this part of the study? We will select 400 women of reproductive age to participate. They will be selected from the 8 control (25 women per village) and 8 intervention (25 women per village) villages.

Compensation: We will provide you with 35 Quetzales (equivalent to 5 US dollars) at the first visit, and 50 Quetzales at both the 4-5 month and 12-13 month visits. If you do not have a mobile phone, we will loan you one until the project ends, so that the Ecolectivos study team can communicate with you. This phone will only be able to receive incoming calls.

Do you have any questions? Are you interested in participating?

Part 3: Collect trash produced in your home for 1 week.

In this part, we want to estimate the amount of waste produced in your home. We will do this by asking you to collect your trash for one week. We will then weigh the trash. By doing this, we can estimate air pollutants that would have been produced by burning trash in your home.

What will happen if you decide to participate in this part of the study?

Trash collection at home: We will ask you to collect all of the trash that your family produces for 1 week. We will give you a large bag for collection of trash to keep your home clean/free of insects. We will weigh the bag of trash and transport it to either a recycling center or the waste facility in Jalapa. This activity will occur 3 times during the study, at baseline (the start of the study), 4-6 months and 12-13 months from the baseline visit.

Questionnaires: We will ask you questions about your household size and trash disposal practices. This survey will take about 15-20 minutes.

How many people will participate in this part of the study? We will select 80 women of reproductive age to participate. They will be selected from the 8 control villages (40 women) and 8 intervention (40 women) villages.

Do you have any questions? Are you interested in participating?

Part 4: Wear a silicone wristband

In this part of the study, we will ask you to wear a silicone wristband for 8 days, at 2 different times: at the start of the study, and at about 4 – 6 months. Silicone wristbands can absorb chemicals from the environment, including those that are in smoke, and from your skin. This will help understand your exposure to chemicals.

What will happen if you decide to participate in this part of the study?

Silicone wristband: We will ask you to wear a silicone wristband for 8 consecutive days and nights. You can place it on whichever wrist is most comfortable to you. You will always keep the wristband on while doing all activities, including bathing, eating and sleeping. After exactly 8 days and nights, you will remove the wristband. For example, if we placed the wristband on your wrist Monday morning at 10 am, you should remove it the following Monday morning at 10 am. We will ask you to write down the day and time you removed it. We will give you a container for storing your wristband until study staff can collect it from you.

Questionnaires: We will ask questions about your activities, where you spent time, whether you used any products like lotion, liquid hand soap, or insect repellent on your body, and whether the wristband came off at any time, or if you removed it.

How many people will participate in this part of the study? We will select 150 women from 6 villages to participate, 75 from 3 control villages and 75 from 3 intervention villages.

Compensation: You will not receive any additional compensation for this part of the study.

Do you have any questions? Are you interested in participating?

Part 5: Villages randomized to the intervention

People in these villages will participate in village working groups that will develop strategies to reduce plastic waste and plastic burning in their village.

Village members in selected villages will work together to develop strategies that they can use to reduce plastic waste and burning of plastic. We will ask you to participate in these working groups every week for 12 weeks. With other members of your village, you will brainstorm actions that you and your village can take to reduce plastic burning. After this, we will ask the people who participate in these working groups to choose one action or project that they can dedicate to achieving over the next 9 months.

What will happen if you decide to participate in working group activities?

Working groups: You may be asked to participate in working groups. We would like you to commit to coming to at least 10 meetings. Each meeting will last about 1-2 hours.

Questionnaires: We will ask questions about you and your family, such as your age, sex and race/ethnicity. We will also ask you to answer questions about the waste practices in your home, such as when/where you burn waste, what types of waste you have, and the amount of waste your house makes in a week. We will ask about your experience and knowledge with recycling. We will also ask you about your experience in the working group and what you learned. These questionnaires will take about 10-15 minutes. We will ask you to complete these questionnaires either before, during or after each working group. Each week, after the workshops, you will be given a questionnaire that you must answer at home, which you will need to bring back to the next working group.

Focus groups: You may be asked to participate in a focus group with members from your village. If you are selected, we will ask you about the success of the working groups in your village. Questions may include what you thought of the working groups, what you learned from the activities, and what changes you have seen in your village that came about as a result of these working groups.

Promotora: You may be asked to be an environmental health community worker (*promotora*) for your village, along with 1 or 2 other people. This will involve staying in regular contact with the other study participants through home visits and monthly phone calls, for 9 months after the workshops end; participate in meetings, monthly calls, interviews or follow-up meetings with the members of the study team; and establish communication with the other members and leaders of your community. If you are asked to be a community promotora, it will be because at the end of the workshops, you have voluntarily chosen to represent your community.

Promotora visit group: You may be asked to be part of a small group who will receive monthly home visits or phone calls from a *promotora* who will be working with us on working group activities in your village. You may also be asked to attend meetings in your village after the working groups are done. If you are selected, you will be asked about some plastic waste management practices and the working groups in your village. Questions may include what

intervention activities you participated in, what actions you learned in the workshops that you have been able to implement, and what changes you have or have not seen in your household and village as a result of these working groups. Each monthly visit by the *promotora* will last about 20 minutes.

Results dissemination meeting: At the end of the study, we may ask you to participate in a village activity where we will discuss the ideas and projects that resulted from the working groups. This meeting will last around 4 hours.

How many people will participate in this part of the study? We will randomly select 8 villages to be in the intervention group that will take part in the working groups. We will invite adults from these 8 villages to participate.

Compensation: If you attend at least 10 of the 12 working group sessions, you will receive a small gift like a reusable shopping bag. You will also be eligible to be part of a raffle drawing at the end of the working group sessions where we will award two prizes of 200 Quetzales (equivalent to 25 US dollars). We will do these raffles in each of the 8 villages where we hold the working groups. If you become a promotora, and you do not have a mobile phone, you will receive one, along with a data plan, so that you can communicate with study participants and Ecolectivos staff. If you already have a mobile phone, you will be given airtime worth Q100 monthly. In addition, you will receive a maximum compensation of up to Q500 for the activities carried out monthly for up to 9 months. This amount will depend on the number of participants visited, which may vary, depending on how many promoters there are in the village.

Do you have any questions? Are you interested in participating?

All Participants

Risks and Discomforts

There is no risk to your health by participating in this study. It is possible that some of the questions we ask may make you feel uncomfortable or upset. There is the possibility of a loss of the confidentiality of the study data, but our team will take measures to avoid it. There is no known risk of wearing the smoke monitoring devices or having them in your house. Wearing the apron or vest may be uncomfortable, but if you experience discomfort, please talk to us about this. There is no known risk of wearing the wristbands. You may decide to stop participating in the study at any time, without any negative consequences. You just have to let a member of our group know that you no longer want to participate. You may also choose not to answer questions we ask and refuse to participate in any part of the study.

Benefits

There will be no direct benefits to you for participating in the study. The results will help us learn more about the smoke problems generated by burning plastic in your village, which will help plan future research.

Village Compensation

If you are in a *control* village, your village will receive small trees for local forestation. Community leaders will choose which community areas can be reforested, and they will organize this with study staff.

If you are in an *intervention* village, your village will receive materials and/or necessary equipment to carry out the chosen project in an efficient way.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Other Options Outside this Study

You may choose not to participate.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory University employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Storing and Sharing your Information

We will write down your name and other personal information, such as the location of your home. However, for privacy, this information will only be used by our research team. Your information will be handled as confidentially as possible. All consents and data forms will be kept safe and only study staff will have access to them. All information on sheets of paper will be kept secure and stored in a locked file at the Universidad del Valle de Guatemala for 5 years, after which we will destroy it. The information collected on an electronic tablet will be stored on the researchers' computers and can only be accessed with a password. Data will be stored on REDCap, a secure web-based application. The information stored on the computers will not have any information that can identify the participants. Your name or any other personal information will not be used in any summary, report, publication or conference that may result from this study without your approval. Only government agencies and university employees in Guatemala and the United States supervising the study will be able to review the data, but they are also committed to keeping this information private.

Once the study has been completed, we will hold a meeting with participants to tell you about the results of the study. We will not give you your individual results from this study.

Withdrawal from the Study

You have the right to leave the study at any time without penalty. Simply tell a member of the research team that you no longer want to participate in the study. You can also decide not to answer any questions we ask, and you can refuse to participate in any part of the study. Your participation is completely voluntary.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Contact Information

You can talk with the study staff about any questions, concerns or complaints you have about this study.

In Guatemala, you can call the project office at [REDACTED] This number is available Monday through Friday from 8 am to 5 pm. You can contact [REDACTED], who is in charge of the study at Universidad del Valle de Guatemala, at [REDACTED]. You can also go to the project office located at [REDACTED] where our team can answer any questions about the study, or put you in touch with the principal investigator in Guatemala.

If your questions are related to your rights as a participant, you can speak with [REDACTED], president of the Research Ethics Committee of the Center for Health Studies at the Universidad del Valle de Guatemala, by calling [REDACTED] ext [REDACTED]. This committee handles the protection of volunteers who participate in research projects. You can reach her from Monday to Friday from 8 am to 5 pm.

Consent and Authorization
TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study, ECOLECTIVOS. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

Please complete this section by marking "yes" or "no" and then sign at the end.

The participant agrees to participate in the study		
1.	I confirm that I have read (or they have read to me in front of a witness) the information sheet dated 8 February 2024 (version 6.0). I have received a copy. I have had the opportunity to consider the information and ask questions. My questions have been answered satisfactorily.	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	I understand that my participation is voluntary and I am free to withdraw from the study at any time or withdraw from any component of the study without indicating reason and without penalty. The signature does not imply loss of individual rights according to the laws of Guatemala.	<input type="checkbox"/> Yes <input type="checkbox"/> No
3.	I agree to participate in the rapid community assessment interview (Part 1).	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.	I agree to participate in the measurement of personal exposure to smoke in the air (Part 2). This may include collection of urine samples, wearing a personal air pollution device for 24 hours, and completion of questionnaires.	<input type="checkbox"/> Yes <input type="checkbox"/> No
5.	I agree to collect trash produced in my home for 1 week (Part 3).	<input type="checkbox"/> Yes <input type="checkbox"/> No
6.	I agree to wear a silicone wristband at 2 different times, for 8 days each time (Part 4).	<input type="checkbox"/> Yes <input type="checkbox"/> No
7.	I agree to participate in the working groups aimed at coming up with strategies to reduce plastic waste in my village (Part 5). This may include questionnaires, participation in working groups, focus groups, home visits and meetings, and participation in designing a strategy to reduce plastic waste and plastic burning in my village.	<input type="checkbox"/> Yes <input type="checkbox"/> No
8.	I agree to be contacted by study staff to see if I want to be a <i>promotora</i> (Part 5).	<input type="checkbox"/> Yes <input type="checkbox"/> No

Name of Subject

Signature of Subject (18 or older and able to consent)

Date **Time**

Signature of Legally Authorized Representative

Date **Time**

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion

Date **Time**