

# Household air pollution and health: a multi-country LPG stove intervention trial

NCT02944682

Informed Consent Form template in English dated May 25, 2018

**INFORMATION SHEET (PREGNANT WOMAN & CHILD FORM)**  
**Information about a Research Study**

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**Consent Version Date:** 25 May, 2018

**Study IRB #:** 89799

**Study Title:** Household air pollution and health: a multi-country LPG stove intervention trial  
(HAPIN)

**Principal Investigator:** (add local investigator)

**Study Contact Telephone Number:** (add local phone number)

**Study Contact Email:** (add local email)

**Funding:** US National Institutes of Health

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Hello. My name is \_\_\_\_\_ and I work with [LOCAL INSTITUTION]. I would like to tell you about a research study we are conducting to see if you would like to participate.

The purpose of this research is to study the health of pregnant women, their children under one year of age, and older adult women, who are exposed to smoke from wood or biomass cooking stoves in their home. Smoke from these stoves may be a risk to the health of those who breathe it for many months and years.

You are being asked to take part in this study because you are at least 9 weeks and less than 20 weeks pregnant, you are between 18-34 years of age, you do not smoke, you plan to stay in the study area for the next 12 months, and you have an open fire or traditional stove. We would like to invite **you and your unborn child** to participate in the study during your pregnancy and the first year of your child's life.

I will now explain more details about the research study to you. Research studies include only people who **choose** to take part. It is **entirely up to you** to decide whether to participate or not. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask us.

A description of this research study will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

I will now tell you about the purpose of this study and what you will have to do if you choose to participate.

**Why is this study being done?**

Smoke from wood/biomass cooking stoves may be a health risk to those who breathe it for many months and years. This study will look at the effects of breathing smoke from cooking stoves when at home during pregnancy, on child health during the first year of life, and on older

adult women. We are interested in the health benefits of reducing this smoke exposure when households switch from biomass to cleaner fuels such as LPG or gas.

We hope the results of this study will help the researchers better understand the health problems caused by smoke inside the home.

This study is being conducted with support from the National Institutes of Health and others in the United States. The investigators will not gain money or any financial incentives from the results of this study.

This project has been reviewed by the [Institutional Review Board or Ethics Committee] in this country. Governmental authorities are aware of this project and have given us permission to conduct this study and seek participants here.

### **How many people will take part in this study?**

About 800 pregnant women and their babies will be taking part in this study in this country. Additionally, approximately 200 older adult women living in the same homes as the pregnant women and their babies will be taking part. Women in 3 other countries are also participating.

### **What will happen to me and my baby if I take part in this research study?**

If you choose to participate, and we determine that you meet certain conditions, your household will be randomized to use a type of cookstove. This means you will be randomly assigned to a cookstove group based on chance, like the flip of a coin. One group of participants, the 'control' group, will continue to cook the same way they are cooking now. The other group, the 'intervention' group, will be assigned to use a table-top liquid petroleum gas (LPG) stove for cooking.

Neither you nor the researcher can choose which group you will be in. Each participating household has an equal chance of being in either group. You may have neighbors who are in a different group. We need to have households in both groups so we can compare whether there are different health risks with the different types of stoves.

You will be compensated for your participation in this study until your child is one year old. If you are in the LPG stove group you will receive free of charge a table-top LPG stove, an LPG refillable tank, and a supply of gas for approximately 18 months.

If you are in the control group you will receive various household or personal items throughout the study. At the end of the study, when the child is one year old, you will receive (an LPG stove and gas tank or a big item).

Regardless of which group you are in, you should continue to take any precautions you currently take to avoid smoke exposure in your household.

### **What will I be asked to do?**

#### **If you are in either group, we will do the following:**

- **Home health visits and questionnaires during and after pregnancy:** We will make 3 health visits to your house during your pregnancy and 4 visits after your child is born. At the

first visit, we will ask you general questions about household members, your house, and the food you and your family usually eat. We will also ask you about your current and past pregnancies and health conditions. We will also make some health assessments about your unborn baby using an ultrasound machine, like measuring the fetal heart rate and growth. At 2 other visits during your pregnancy and at 4 visits after your pregnancy, we will repeat some of these questionnaires and measurements. You can choose not to answer any question asked of you. If you are having any health problems, we will refer you to the nearest health center for an examination by a physician.

- **Blood pressure measurements:** We will measure your blood pressure 3 times during your pregnancy. At each visit, we will take 3 blood pressure measurements, 2 minutes apart, while you are sitting down. We will wrap a device around your arm. This procedure is very safe and there is no risk of harm or pain to you. This device will also measure your heart rate. After we are finished we will report to you the results. If you are found to have a systolic blood pressure 140 mmHg or higher, or a diastolic blood pressure 90 mmHg or higher, at 2 measurements at the same visit, we will refer you to the nearest health center. Your height and weight will also be measured at some of these visits.
- **Urine sample collection:** Smoke may affect certain chemicals in urine, and we will measure those chemicals. You will be asked to give 6 samples of urine, one at each of the home visits during your pregnancy, and 3 at home visits after your child is born. Similarly, we will ask that your child give 3 samples of urine, one when the baby is about 3 months old, one when the baby is about 6 months old, and one when the baby is about 12 months old. We will ask you to collect the urine at your home in containers provided by the study and keep it stored in a cooler, given by the study, until we pick it up the following day. Many parents find it easiest to collect their child's urine using a urine bag. For children wearing disposable diapers, we may be able to take the sample directly from the diaper.
- **Blood sample collection:** Smoke may affect certain chemicals in blood, and we will measure those chemicals. You will be asked to give 6 very small samples of your blood, at the same home visits as the urine samples. Similarly, we will ask that your child give 4 very small samples of his or her blood, one at birth and 3 at the same home visits as the urine samples. This procedure is very safe for you and your child, although you might feel a little pain during the procedure. After thoroughly cleaning your finger with a cloth containing alcohol, we will use a small needle to prick your finger while you are sitting down. Your child will be pricked in the heel or finger with a small needle to minimize pain. We will drip 4-5 small drops of blood onto a piece of paper and into a small tube, and then we will hold a gauze over your finger to stop any bleeding. We will give you and your child a bandage afterwards. Your samples will likely be analyzed in a batch with all other samples at the end of the study, and the chemicals we are measuring would not be relevant for clinical diagnoses. We will therefore not share the results of most of the blood tests. We will, however, tell you the results of your hemoglobin (anemia) test.
- **Other home visits:** We will also make other home visits throughout the study, described in the sections below. (See the *Smoke and stove use measurements*, *Newborn health visit*, *Monthly health checks* and *Growth and development visits* sections).

If you are in the LPG stove group, we will also visit your home to install your stove, to talk to you about your stove use, and to check on or fix your stove and deliver gas as needed. You will need to contact our study staff to arrange for tank refills. We will show you how to use

and maintain the stove and tanks safely, and you will be provided with a contact telephone number in case the stove or tank needs repairing.

- **Smoke and stove use measurements during and after pregnancy:** We will measure your exposure to household smoke 3 times during your pregnancy. We will also visit your baby when s/he is about 3 months old, about 6 months old, and about 12 months old to measure the levels of household smoke s/he is breathing. These visits may be at the same time as the health visits, or they may be separate visits.

To do this we will:

- For 3 visits during pregnancy, we will ask you to wear an apron or vest which contains small devices to collect smoke for 24 hours (1 day). The apron or vest will contain a pump that makes a small humming noise. We will also ask you a few questions.
- For 3 visits after your child is born, we will have the child wear a small device for 24 hours (1 day), which will help us determine if s/he is exposed to smoke. This will clip onto the child's clothing or be worn as an armband and will not interfere with his or her normal activities.
- We would like you and your child to wear these devices for 24 hours (1 day). After 1 day we will return to remove the devices and ask a few questions. You should not change your behaviour while wearing these devices. You should do your normal activities just as you always would. If you need to bathe or sleep you may take it off, but please keep it as close to you as possible. Please do the same for your child. Please keep this on the same child for the entire day.
- We will also measure the smoke in your kitchen for 24 hours (1 day). A small device that makes a small humming noise will be put in your kitchen to take the measurements along with other small devices.
- When we return to collect the devices from your home, we will also ask you some questions about the use of your stove, your activities, and where you and your baby spent most of your time during the last 24 hours (1 day).
- This equipment is not dangerous. The personal device weighs less than  $\frac{1}{2}$  kg and holds a pump that simply helps to measure the smoke. There is a light sensor that measures the amount of light around you. If you want to stop your participation and stop wearing the device, or have your child stop wearing the device, you may take it off at any time with no consequences. If the devices are stolen or broken you will not be responsible for this.

At the beginning of the study, we may also place small temperature sensors on the cooking stove(s) in your home and leave them there for the duration of the study.

- **Newborn health visit:** We would like you to inform us of the birth of your child within 24 hours of birth. After being informed about the birth, we will visit your home or the hospital to ask you some questions about the birth and to measure your baby. We will measure the weight, length and head circumference of your baby, and take a blood sample. These procedures are safe for your baby, and we will try to minimize any stress to the baby associated with these procedures. We may check your medical record to determine delivery details. If your baby is having any health problems, we will refer you to the nearest health center for an examination by a physician.

- **Monthly health checks:** After your baby is born we will briefly visit your home every month until the baby turns 1 year old. At these visits we will check if the baby has any acute respiratory disease like pneumonia. We will also ask about what you feed your baby. If we detect any acute respiratory disease, an ultrasound will be used on your baby to get better information to confirm the disease diagnosis. In some cases, this may be done in a clinic; in other cases, directly by the staff member or health worker in your home. This procedure is safe for your baby. If your baby is having any health problems, we will refer you to the nearest health center for an examination by a physician. During some of these visits we might ask you some questions about your gas stove and tank and may want to observe it to make sure that there are no technical problems. If there are, we will call the repair team who will come and fix them.
- **Health facility visits:** We ask that you to bring your baby to a health center if your baby has any breathing problems. A study team member there will ask you some questions about your baby's respiratory health. We will also measure how fast he or she is breathing, and the level of oxygen in your baby's blood, by placing a small probe on his/her finger. This is a painless and non-invasive test. If there are signs of respiratory illness during our evaluation, we would like to collect ultrasound images to get a better view of your baby's lungs. This procedure is safe for your baby and does not hurt them. We may also look at your baby's medical records to get a full picture of your baby's respiratory illness.
- **Growth and development visits:** Every 3 months we will briefly visit your home to measure the weight, length and head circumference of your baby. We will also observe the behaviour of your baby and ask you a few questions about your baby's daily activities and what you feed your baby.

All visits are expected to last between 30-90 minutes.

**These visits should not replace your routine prenatal and postnatal exams.** You should continue to go to your doctor's scheduled visits even if you do not participate in the study.

**Will you save my and my baby's samples or research data to use in future research studies?**

As part of this study, we are obtaining data, ultrasound images, and urine and blood samples from you and your child. We would like to use the data, ultrasound images, and urine and blood samples from you and your child for other research studies in the future. These future research studies may provide additional information that will be helpful in understanding the health effects of smoke from cooking stoves, but it is unlikely that what we learn from these studies will have a direct benefit to you or your child. If you agree, this means we will store the data, ultrasound images, and urine and blood samples from you and your child and may use them for studies going on right now as well as studies that are conducted in the future.

We would also like your permission to share the data, ultrasound images, and urine and blood samples from you and your child with other researchers who study similar research topics. We may also share your and your child's research data with large databases of information called "repositories" for broad sharing with the research community. If your and your child's research data are placed in one of these "repositories" only qualified researchers who have received prior approval from institutions that monitor the use of the data will be able to look at your and your child's information.

All of your and your child's data, ultrasound images, and urine and blood samples will be stored without any personal information such as your name or address. We will only use your and your child's unique study number.

### **How long will my baby and I be in the study?**

Participation in the study will be during your pregnancy and for 1 year after you give birth.

### **Can I stop being in the study?**

Yes. You can decide to stop at any time, without giving any reasons, and without any penalty. Just tell the study staff member right away if you wish to stop being in the study. You can choose not to answer any question that is asked of you, and you may refuse to participate in any part of the study.

The researchers also have the right to stop your participation for any reason. This is especially true if they believe it is in your best interest, or if you were to repeatedly refuse to participate in key study procedures that are important to the study outcomes. It is important for us to collect the study data, and it is therefore important for you to actively participate in the study.

### **What side effects or risks can my baby and I expect from being in the study?**

Some of the questions during the visits can make you feel uncomfortable or annoyed; you are free to refuse to answer any question at any time. During the 3 pregnancy visits, you will have an ultrasound exam using an abdominal probe. The ultrasound procedure will not harm you or the fetus. The finger and heel needle pricks may cause temporary discomfort, but will not harm you or your child. There is no known risk involved with the urine collection. The assessment of your baby's weight, length, and development, are non-invasive and pose minimal to no risk.

There is no known risk of wearing the smoke monitoring devices, or of leaving the device for measuring the smoke inside your home. The equipment only absorbs a small amount of smoke. During the time the devices are in your home, you do not have to do anything special; just go about your daily routine. Wearing the apron or vest may be uncomfortable, and if you experience discomfort, please talk to us about this.

If you are in the LPG stove group, if the gas stove is not installed, maintained and used properly there is a risk of burns as with open fires and other stoves. Damaged or leaking gas tanks can lead to an explosion. If a valve is leaking or left open, air can diffuse into the gas tank, which can form a flammable mixture that can explode. You will receive safety trainings about how to properly maintain and use the gas stove and tank. Our team will also check regularly on your gas stove and tank and arrange for repairs as needed.

For more information about risks and side effects, contact one of the researchers or staff members.

### **What are the costs of being in this study?**

There are no costs for being in the study.

**Are there benefits to being in the study?**

You will be compensated for your participation in this study until your child is one year old. If you are in the intervention (LPG stove) group you will receive free of charge a table-top LPG stove, an LPG refillable tank, and a supply of gas for approximately 18 months. We will show you how to use and maintain them safely, and you will be provided with a contact telephone number in case the stove or tank needs repairing. At the end of the study, the stove and tank are yours to keep at no charge.

If you are in the control group you will receive various household or personal items throughout the study. At the end of the follow-up period, when the child is one year old, you will receive (**an LPG stove and gas tank or a big item**).

Any household member (mother, child, older adult woman) may decide to discontinue their participation in the trial at any time, for any reason. However, if any participating household members discontinue participation in the trial prior to the child's first birthday, any compensation items not yet provided, including LPG and gas not yet delivered to intervention households, may not be delivered.

You will not be paid to participate in this study. There will not be other direct benefits for your family. However, the information you provide may help us and other researchers working in the community understand the effects of smoke on the health of children, pregnant women, and older adult women. We hope this will help promote future investigations and improve living conditions in this country.

No matter which group you are in, if as a result of study measurements we find that you or your baby have a health condition, for example, high blood pressure, we will refer you to the nearest medical care facility for treatment.

**What other choices do I have if I do not agree to be in this study?**

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You can continue to seek medical care at hospitals and health centers and with traditional birth attendants, community health workers, nurses and physicians.

**Will information about my baby and me be kept private?**

All of the information we collect from you and your baby will be kept private. Your name, the name of your family, and other personal information such as the location of your home will be collected. However, for privacy purposes this information will only be used by our research team. Your information will be handled as confidentially as possible. Urine and blood samples will not have personal information about you. The urine and blood samples will be kept in a freezer in a locked laboratory. All questionnaires, consents, and data forms will be kept secure and only study staff will have access to them. All information on paper forms will be kept secure and locked within a locked filing cabinet; other information will be on computers accessible only to study staff. Your name or any other personal information will not be used in any summaries, reports, publications or conferences that may result from this study without your approval in a separate consent.

**Certificate of Confidentiality**

There is a Certificate of Confidentiality from the US National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. We will rely on the Certificate to refuse to give out study information that identifies you. For example, if we received a subpoena for study records, it would not give out information that identifies you.

The Certificate does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop us from making the following disclosures about you:

- Giving government public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation

**What are my rights if I take part in this study?**

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way.

**What will happen to the results of this study?**

The results of this study will be published in a journal. We will also organise meetings in [INSERT CAPITAL OF DISTRICT WHERE STUDY BEING CONDUCTED] where we will summarise and explain the results of the study. The results will be available in 5 years' time.

**Who can answer my questions about the study?**

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

In [COUNTRY], you can contact the project office staff [INSERT CONTACT DETAILS]. You can also call [NAME], who is in charge of the study at [INSERT CONTACT DETAILS]. You can talk to [NAME OF ETHICS MEMBER], president of the Ethics Committee at [INSERT CONTACT DETAILS] during business hours. The committee is concerned with the protection of volunteers in research projects.

**Do you have any questions?**

**Are you willing to participate?      1. Yes (Take consent – next page)**

**2. No (Stop the interview)**

**CONSENT FORM****Study Title:** "Household air pollution and health: a multi-country LPG stove intervention trial (HAPIN)"***Please complete this section by ticking "yes" or "no" and then signing at the bottom if all answers are "yes".***

<b>Patient consent to participate in randomized controlled trial</b>		
1.	I confirm that I have read (or have been read in front of a witness) and understood the information sheet dated 25 May 2018 (version 3.0) and have been given a copy to keep. I have had the opportunity to consider the information, ask questions, and have my questions answered satisfactorily.	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2.	I understand that I will be randomized to either the LPG stove group or the control (my current stove) group.	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3.	I understand that my participation is voluntary and that I am free to withdraw from the study at any time or from any study component without any reason and any penalty.	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4.	I agree to participate in the personal and household measurement of smoke from cooking stoves.	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5.	I agree to participate in the ultrasound examination, urine sample collection, blood sample collection, and other health assessments (blood pressure, height, weight).	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6.	I agree that my data, ultrasound images, and urine and blood samples can be stored and used for future research or with other investigators for future research.	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No
7.	I agree that my child's data, ultrasound images, and urine and blood samples can be stored and used for future research or with other investigators for future research.	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No
8.	I agree to participate in the above study.	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No
9.	I agree to allow my child to participate in the above study.	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Name of Participant \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

Name of Witness \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_  
(If participant not able to read consent form)

Name of Person Taking Consent \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

1 copy for participant, 1 copy to be kept with local research institution