Better Memory with Literacy Acquisition Later in Life

NCT number NCT04473235

Date February 21th, 2021

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

You are being invited to participate, as a volunteer, in the study “Effects of late literacy on brain memory and connectivity”. The objective of the research is to evaluate the effects of late literacy carried out by the Education for Youth and Adults (EJA) program on memory and brain functions. You were selected for the study because you are interested in enrolling in the EJA program and because you are between 30 and 90 years old. Your participation is not mandatory. At any time, you can withdraw from participating in the study and withdraw your consent. Your refusal, withdrawal or withdrawal of consent will not cause you any loss or compromise your classes at EJA.

You will be interviewed about general aspects of your life, current and past health problems, the presence of symptoms of depression, alcohol use and health problems in the family. You will also undergo memory and reasoning tests. This evaluation will be carried out by the researchers and their assistants and will have a total duration of one and a half hours. To avoid mental fatigue or any embarrassment, we will conduct the interview and tests in quiet places, at a time that is good for you.

If we eventually identify that you have a health problem and that you are not under medical supervision, we will refer you to receive appropriate medical care and follow-up. The referral will be made by means of a report in which we will describe which problem has been identified that must be delivered to the nearest health clinic to your home or to your doctor.

In addition to the interview and the memory tests, you can also do two other tests: the brain MRI blood tests.

The MRI will be performed twice, once this month and the other six months after the first exam. This test can cause discomfort in the ears, because the device emits a loud sound for about 30 minutes. Ear protectors will be used to reduce this discomfort.

For the blood tests, we will collect 20 ml of blood (equivalent to a tablespoon) from a vein in the arm. The risks associated with this procedure are minimal, with pain and bruising at the blood collection site. The collection can cause discomfort and, to decrease this discomfort, it will be performed by a trained professional. The blood sample will be sent to a laboratory at the Faculty of Medicine of the Federal University of Minas Gerais. The purpose of this collection is to measure the proteins present in the blood that are related to the proper functioning of the brain. After processing, the collected sample will be stored in a freezer at the Faculty of Medicine of the Federal University of Minas Gerais for a period of five years. The sample stored for these five years may be used in future research. In the case of using the sample stored in future research, the researcher must obtain a new consent from you.

At any time, you can withdraw your consent to keep and use the blood sample. The withdrawal of your consent must be made in writing and signed by you or your legal representative, and the researcher will return all existing blood samples to you.

By agreeing to participate in the research, during the first six months of classes at EJA you will receive either specific training in reading and writing (literacy training) or classes in geography, history and science. In the next six months, you will change groups: whoever was learning to read and write will take classes in geography, history and science and whoever was taking these classes will learn to read and write. You will

not know which group you are enrolled in. At the end of 12 months, both groups will have received the same training.

Your participation in the research will then consist of two visits with an interval of six months between them. A visit will be made later this month with the interview, memory tests, MRI and blood test. The other visit will be made six months after the first and the same procedures will be carried out again. Therefore, the total time you will participate in the survey will be six months.

The researcher guarantees that you will have access to all the results of the tests performed during the research, both the blood tests and the MRI.

MRIs and blood tests will be performed at Clínica Axial at Av. Bernardo Monteiro, 1237 - Funcionários, Belo Horizonte. You will receive assistance to cover transport costs to the exam location.

Your participation in the research will not be remunerated. All expenses that you and your companion incur when participating in the survey will be paid by the researcher. You will not get any direct benefit or advantage from your participation in this study and there will be no increase in EJA program test scores for your participation in the research.

The data obtained through this survey will be confidential and will not be disclosed with the names of the participants, in order to guarantee the confidentiality of their participation. The unidentified data will also be shared with the University of California, San Francisco (UCSF). All medical information will be subject to the regulations of Hospital das Clínicas - Federal University of Minas Gerais regarding the confidentiality of medical information. The responsible researchers are committed to presenting the results obtained in scientific events and publications without any identification of participating individuals or institutions.

In case of doubts about the project and your participation in it, you can contact Dr. Elisa de Paula França Resende or Professors Paulo Caramelli and Leonardo Cruz de Souza, by phone or address below:

Contacts of the responsible researcher: Paulo Caramelli, professor at the Faculty of Medicine of the Federal University of Minas Gerais.

Address: Av. Professor Alfredo Balena, 190, sala 246, Santa Efigênia, Belo Horizonte, MG - CEP: 30130-100

Phones: (31) 3409-9747; (31) 99971-5001

Email: elisa.resende@gbhi.org, caramelli@ufmg.br

In case of doubts related to ethical aspects, or if you have difficulty in contacting the responsible researcher, you can contact the Research Ethics Committees described below:

1) Research Ethics Committee - CEP - of the Federal University of Minas Gerais: institutional body that aims to protect the well-being of individuals participating in research carried out at the University.

Address: Av. Antônio Carlos, 6627, Administrative Unit II - 2nd Floor - Room: 2005, Pampulha - Belo Horizonte - MG - CEP: 31270-901

Phone: (31) 3409-4592

Opening hours: from 9: 00h to 11:00 and from 14: 00h to 16: 00h

Email: coep@prpq.ufmg.br

2) National Research Ethics Commission - CONEP: National Health Council commission created with the function of implementing the norms and regulatory guidelines for research involving human beings. It

works together with a network of Research Ethics Committees organized in the institutions where the research is carried out.

Address: SRTVN 701, Via W 5 Norte, PO 700 Building, 3rd Floor, Asa Norte - Brasília - DF - CEP: 70.719.040

Phone: (61) 3315-5877

Opening hours: 8am to 6pm

Opening hours "on line": 8 am to 8 pm

Email: conep@saude.gov.br

If you agree to participate in this research, sign at the end of this document, which has two copies, one of which is yours, and the other, of the responsible researcher.

I confirm that Dr (a) ._____ explained to me the purpose of the study, the procedures to which I will be submitted, the risks, the possible discomforts and that participating in this study will not bring me any direct benefit. I have read and understood (or it was explained to me) this consent form and I am in full agreement to participate in this study.

Belo Horizonte, ____ of _____ of _____.

Signature of participant: _____

Signature of the researcher: _____