INFORMED CONSENT FOR PILOT ESM STUDY: ADOLESCENTS

Title of the study:	Building resilience and resources to reduce depression and anxiety in young people from urban neighbourhoods in Latin America (OLA)
Principal investigators:	XXX (Country), Prof. Stefan Priebe (UK)
Date and version:	7th September 2020 (Version 1.0)

We are researchers from XXX and Queen Mary University of London in the UK, and we want to invite you to participate in a research study. Please read this document before deciding to participate in the study, and if you have any question or do not understand a section, please feel free to ask the research team.

1. What is the purpose of the study?

During adolescence it can be common for people to feel distressed, some people may call this mental distress, depression or anxiety. Adolescents and young adults who live in big cities more commonly experience stressful events such as conflict, poverty, substance misuse and social isolation. This includes adolescents and young adults in Latin America, which is the most urban part of the world. Although many individuals experience stressful events, a lot of people do not develop mental distress, and when people do become distressed, half will recover within a year.

We have developed a study to identify resources that help young people to prevent or recover from mental distress, including depression and anxiety. We will focus on adolescents and young adults who live in three large Latin American cities: Buenos Aires, Bogotá and Lima.

The study aims to develop new ways of asking about resources that help young people prevent or recover from mental distress. We would like to explore a method called 'Experience Sampling Methodology (ESM)', which is a way of asking about your mood, thoughts and activities as you go about your day using a mobile phone App. The information you provide will help us learn about your opinions of ESM, improve and finalise our methods, which will form a key part for the next stage of this research study.

2. What does your participation entail?

If you decide to participate, we will invite you to test our ESM App, called eMoodie, on your phone over a period of 7 days, and then afterwards ask you to provide us with your feedback, including your experience of participating, whether you encountered any problems taking part in the study, and your thoughts on any improvements to the study procedures.

First, you will meet with a member of the OLA research team, who will help you to install the ESM App on your mobile phone. The App will ask you to complete a short questionnaire, that will take about 2 minutes, 5-8 times a day at random points during the day (during the hours that you are awake), over 7 days. On school days, the App will ask you to complete the questionnaire 5 times per day, and on weekend days, the App will ask you to complete the questionnaire 8 times per day. The questionnaire will ask you how you are currently feeling, including how relaxed you currently are, where you are currently, what you are currently doing and thinking about, and who you are currently with.

During this first meeting, the researcher will show you how to use the App, practice answering a questionnaire, and they will answer any questions you might have. You will also agree on the day on which you will start completing the questionnaires. This first meeting will last up to 30 minutes. If you are unable to meet face-to-face, we will ask to meet you online, through a video call, or to speak over the phone.

When it is time to complete the questionnaire, the App will send you a notification on your mobile phone. Please respond and answer the questionnaire straight away. If after two minutes you have not completed the questionnaire, then you will get a reminder notification to complete the questionnaire. There will be no further notifications if you do not complete the questionnaire after the second reminder and the questionnaire will be recorded as incomplete.

During the 7 days of completing the questionnaires you will be able to directly contact one of the OLA researchers through the eMoodie App in case you are having any problems, or have any questions, about the study. An OLA researcher will contact you by phone 1-3 times during the study to check how you are finding the study and whether you are experiencing any problems.

After the 7 days of completing the questionnaires, we will ask you to complete a final short questionnaire, where we will ask you about your experience of being part of the study, any problems you may have experienced, and your thoughts on any improvements to the study procedures. The researcher will check all the data has been uploaded, and then you will be able to delete the App from your mobile phone. This meeting will take place face-to-face, via an online platform, or over the phone, according to your preference, and will last up to 30 minutes.

3. What can you do if you do not want to participate in the study or you want to stop participating in the future?

Your participation in the study is and will always be strictly voluntary. This means that it is entirely up to you whether you would like to take part, and it is OK if you choose not to take part, you will not have to explain your reasons. If you do decide to take part, you are also able to change your mind and stop taking part at any time. You can also decide to not answer certain questions if you choose not to. If you decide to stop participating we will ask you if we can use the information we have collected up to that point and we will respect your decision. There will be no consequences if you decide not to take part in the study or decide not to authorise the use of the information collected.

If you decide to part in the study, we will ask you to sign this form to confirm this. Your parent/ guardian will also be asked to sign this form to confirm that they are also happy for you to take part in this study. We will give both you and your parent/guardian a copy of the form. Your signature confirms that you have understood what your participation entails, we have solved any question you may have and you voluntarily accept to participate in the study.

4. What will we do to take care of your privacy and your information?

All the information you provide is confidential (private) and will be used only for the purpose of this study. Your information will be safely shared with the researchers who are a part of this research study from the Universidad Javeriana (Colombia), Universidad Buenos Aires (Argentina), Universidad Peruana Cayetano Heredia (Peru) and Queen Mary University of London (United Kingdom), using an encrypted format that will not include your name.

We will only collect the information that you give to us from completing the questionnaires, we will not collect any other information from you, or from your phones, other than what you agree to give to us.

Your name will never appear on the questionnaires. Instead of your name we will use a code. Only the research team will know which codes belong to which names, and this information will not be shared with other people outside of the team. We will keep the information you give us safely, so it can not be accessed by others outside of the team.

However, if while taking part in the study, you tell us something that makes us concerned for your safety (for example we identify there is a risk of you hurting yourself or others, or you being hurt by others) confidentiality can be broken. If this is the case, we will inform a responsible person at your school or a health provider at the community mental health centre to guarantee yours and others' safety.

The data collected during the study will be stored in the Universidad Javeriana´s servers. The Universidad Javeriana Information and Technology Department complies with all national and international security norms for data protection including assistance regarding computing security related to the research project. The Information and Technology Department´s operating procedures are available at: http://www.javeriana.edu.co/dir-tecnologias-de-informacion/asistencia-de-seguridad-informatica. The protection of the personal data compiled in this project follows the Colombian regulation laws regarding data protection: Law 1581 from 2012 and decree 1377 from 2013. XXX. Data will also be stored in the Queen Mary University of London´s secure servers in-line with the Data Protection Act (2018) and General Data Protection Regulation (GDPR). XXX. The information compiled during this study will be used only for research purposes as it has been previously stated in this form.

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We will keep the study data (information from the study) for 20 years in the UK, however at this point, the data will not include any personal information that could identify you, such as names. Information, such as your names and contact details, which could identify you will be deleted at the end of the study.

5. What benefits might exist if you participate in this study?

A benefit for all participants involved in this part of the study, is that your suggestions and views might be incorporated into how we run the main ESM study to ask about resources in young people, which is the next stage of this study. You will therefore be contributing to the wider aim of the research programme to identify which resources help adolescents and young adults recover from mental distress, particularly depression and anxiety. This may potentially lead to the development of new ways to reduce the burden of mental distress for adolescents in Latin America and beyond.

6. What are the possible risks of participating in this study?

There are no expected risks linked with participating in this study. However, you may feel uncomfortable, or saddened by some of the questions. However, you can decide not to answer a specific question and all the information provided is strictly confidential (private).

7. Will your participation have any cost?

There will be no costs to you to take part in this study. Any costs for you to take part in the study will be provided by the study. This includes transport costs for you to get to meetings with the research team, and for any data that you may need to download and run the app, or to upload your data at the end of the week. The App is designed to be able to work offline, which means that you do not need data during the week to use the App. There will be no costs to receive any of the notifications from the App.

8. Will you be paid to participate in this study?

We will provide you with the following compensation (payment) for the time you have given us to take part in the study:

Additionally, transport costs (XXX) to attend meetings related to the study will be covered.

9. What can you do if you need more information about the study?

You can contact XXX, who is leading the study in XXX, located in XXX, by phone XXX, or by email XXX

This study has been reviewed and approved by the XXX and the Ethics Committee at Queen Mary University of London in the UK. The Committees are made up of people external to the research team, whose function is to ensure the dignity and rights of the participants in research studies are respected. If you have any questions or doubts about your rights as a participant, you can contact XXX.

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I declare that I have received enough information regarding the study. I understand the objectives of the study. They assured me that all the information collected during the study is strictly confidential and that I can contact the researchers or the Institutional Ethics Committee if I need more information. **I agree to these conditions and voluntarily agree to participate in this study**, knowing that I can withdraw at any time, without this decision having any consequences for me.

Participant information

Name of the participant:

Participant national ID number:

Date: _____/_____/_____

Participant signature:

Parent/guardian information

Name of the parent/guardian:

Parent/guardian national ID number:

Relationship to participant: _____

Date: _____/_____/_____

Parent/guardian signature:

Research assistant information

Name of research assistant:

Research assistant national ID number:

Date: _____/_____/_____

Research assistant signature: