

A STUDY OF COUNSELLING IN PRIMARY CARE

Information Sheet for Patients

About this study

You were asked a series of questions about your health earlier today. These showed that you are suffering from a stress-related health problem that may benefit from counselling. We are carrying out a program in many PHCs in Goa, including this one, in which we are evaluating the benefits of counselling for patients with your type of health problem. This brochure will give you information to help you decide if you want to take part in this study.

About the counselling

There will be two groups of patients in the study. All patients will receive the care provided by the PHC doctors. In addition, half the patients will be offered counselling by a trained counsellor.

- If you agree to join this study, you will still see the doctor.
- If you are chosen to be in the group who ALSO get counselling, then you will receive your first counselling session immediately after this discussion. After this first session, you will be offered a further 5 to 7 sessions over the next 2 to 3 months: either the counsellor will come to you at your home or you can come to the PHC, or suggest somewhere else to meet (maybe a friend's house) - whichever suits you best. During these sessions, the counsellor will work with you to understand how stress contributes to your health and social problems, identify possible solutions and suggest methods to cope with these problems.

Making a decision to take part in this study

The decision to take part in the study is entirely your own. This brochure and the Health Assistant are here to provide you with any information you need to help you make this decision. Whether you take part or not will not affect the treatment you receive from the PHC doctor. Even if you decide to take part today, you can change your mind later on without affecting the treatment you receive from the doctor.

How the decision on whether you receive counselling will be made

If you agree to take part, whether you will receive counselling or not will be decided by chance. You will have a 50 per cent chance of being selected in the group to which counselling is given along with doctor's treatment. It is like tossing a coin and there are equal chances of getting a head or a tail. In this study, this decision will be made with the help of a computer which will send the Health Assistant an SMS on the mobile phone to inform whether you should be seen by the counsellor or not. The computer does not know anything about you – it simply makes a choice by tossing a coin.

Your role if you agree to take part in the study

If you are offered counselling, we would encourage you to fully participate to receive the counselling as described earlier- that is, to engage with the sessions and to try to accept

the help that is offered. Counselling sessions will always be arranged to suit your convenience, for example the time and place.

In addition, no matter whether you receive counselling or not, we will ask you to take part in interviews carried out by researchers about 3 and 12 months from today, to find out about your health. Our researchers will always contact you in advance to arrange a convenient time and place to meet you.

Keeping the information we collect from you secure

As part of the study, we will collect information from you. We will write down your answers to our questions, and we will audio record the counselling sessions to ensure that you are receiving the best quality treatment and for training purposes. All the information shared by you, whether collected on paper, audiotapes or computers, will be kept strictly confidential and will not be shared with anyone not pledged to protect the confidentiality of your information.

The risks of taking part in this study

We do not anticipate any risks from your participation apart from the fact that you may find that discussing your health issues and personal problems may be distressing. In our experience, most people do not experience such feelings. We assure you that our counsellors and researchers have been carefully trained to handle such kinds of distress and if required, services of other health experts will be made available to you.

The benefits of taking part in this study

Your participation in the study will benefit you and other people in two ways, First, if you are offered counselling you will receive those sessions from a trained counsellor along with doctor's treatment at no extra cost. As mentioned before, these sessions will be done at your home or wherever is convenient. Counselling may not only help you recover from your health problem, but you will also learn skills that may help you deal with personal difficulties and remain in good health in the future. Second, if our study finds that adding counselling makes treatment more effective, this will help us work with the government to make counselling available in PHCs across Goa and India.

The people and organizations responsible for this study

The study is being carried out by Sangath, Goa's leading health NGO, in collaboration with the Directorate of Health Services of the Government of Goa and the London School of Hygiene and Tropical Medicine, UK. The principal investigator is Dr. Vikram Patel who is based at Sangath.

The person to contact for more information

If you have any questions about this study, you should feel free to ask them now. If you have questions later or wish to withdraw your participation please talk to the Health Assistant in the clinic (Name of the Health Assistant in the concerned PHC). If you have any concerns about the study you can contact Arpita Anand on telephone: 8378965730.

PREMIUM: Consent form for Patients

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of study: PREMIUM, a **PR**ogram for **E**ffective **M**ental health **I**nterventions in **U**nder-resourced health systems

Trial ID:

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Please put a [√] in the appropriate box

YES NO

	<input type="checkbox"/>	<input type="checkbox"/>
Have you clearly understood the information sheet and have had the opportunity to ask questions?	<input type="checkbox"/>	<input type="checkbox"/>
Have you understood that taking part in the research study is voluntary and that you are free to withdraw your participation at any time without giving a reason?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that if the computer selects you to get the counselling treatment, with your permission we will audio-record your conversation with the counsellor for training purposes, and your name will not be linked to the recording?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that all information you share will be confidential?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that a researcher will visit you in your house in 3 months and 12 months time to ask about your health?	<input type="checkbox"/>	<input type="checkbox"/>
Do you consent to be part of the study?	<input type="checkbox"/>	<input type="checkbox"/>
Do you agree to telephone calls by the research team member where necessary?	<input type="checkbox"/>	<input type="checkbox"/>

Name of participant	Date	Signature (literate participant or witness)
Name of researcher/HA	Date	Signature