

PARTICIPANT INFORMATION SHEET

(Patient)

Study Title: “Development of a mobile based intervention framework for difficult to treat patients with severe mental illnesses”.

Investigator(s): Dr. R. K. Chadda
Dr. Mamta Sood
Dr. Pushpendra Singh

Introduction:

You and your caregiver are invited to take part in a research study. Before you decide whether or not to take part it is important for you to understand why the research is being carried out and what it involves. Please take the time to read the following information carefully and discuss it with others if you wish.

(Part 1 tells you the purpose of the study and what will happen to you and your caregiver if he/she takes part. Part 2 gives you more detailed information about the conduct of the study)

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

PART 1

Who is organising and funding the study?

The funding for this study is provided by National Institute of Health Research (NIHR), UK and sponsored by University of Warwick, UK.

What is the study about?

This study would assess the feasibility and effectiveness of implementing a mobile based technology containing a suite of applications/modules as a psychosocial intervention for managing difficult to treat patients with severe mental illness (SMI).

Do you and your caregiver have to take part?

Participation in this study is entirely voluntary and you are free to refuse to take part or withdraw from the study at any time (without having to give a reason) and without, in any way, affecting your future medical care or your relationship with medical staff looking after you. If you wish to participate in this study, we will ask you to sign a consent form to confirm that you have agreed to take part.

What will happen to me if I take part?

You and your caregiver would be given a mobile device, asked to follow up at fixed intervals and undergo assessments at Department of Psychiatry, AIIMS. The said mobile device will be provided free of charge. But you will have to return the device after study completion i.e. 3 months later. Before you start on this study, a doctor will check you're eligibility for the study

What are the possible disadvantages, side effects, risks, and/or discomforts of taking part in this study?

There are no particular risks anticipated in this study. This study will not involve any invasive procedure which might have side-effects.

What are the possible benefits of taking part in this study?

You will be monitored by the research team at AIIMS closely during the study. The study will not immediately benefit you, but if the results of the study are positive, it may help us in providing better psycho-education regarding the illness and its management, improving quality of life by scheduling activities of daily living, and improving medication adherence.

Costs of participating / compensation for participation

Participation in this study will not result in any additional cost to you. Study equipments will be provided by the research team at AIIMS. Participants to the study will not receive any financial compensation

What will happen when the study ends?

After the study ends, the clinical management of the participants will proceed as usual from our centre. The data obtained will be kept secure and confidential. The data will be analysed by the researchers and the findings will be discussed and shared in scientific forums in order to interpret it. The research will not immediately alter the regular treatments you currently receive.

Will my taking part be kept confidential?

Your personal data will be kept confidential. With your permission, identifiable information about you and data collected during the study will be held securely by AIIMS and under the control of the study Investigators. All data collected in this study will be coded and stored on a computer system protected by a password only available to the researchers. No one outside the research team will have access to any identifiable information and all identifiable information and data will be kept securely. Your data will be archived securely for at least five years after the end of study as this is a legal requirement for clinical studies.

What will happen if I don't want to carry on being part of the study?

Should you withdraw from the study, data collected prior to withdrawal will be kept, anonymously, for purposes of future medical research should you agree to that. However, if you wish, your data can be removed from our database. You simply need to inform the research staff what you prefer to happen in this instance. Participation in this study is entirely voluntary and refusal to participate will not affect you and your caregiver in any way including your usual care or any benefits.

What if there is a problem and right to raise concerns?

If you have any concerns about your participation in the study you have the right to raise your concern with a researcher involved in conducting the study or the doctor involved in your care.

Who should I contact if I wish to make a complaint?

If you have a complaint about your participation in the study, you should first talk to a researcher involved in the study. However you have the right to raise a formal complaint. You can make a complaint to a senior member of the research team or to the person below, who is a senior AIIMS official entirely independent of this study:

The Dean (Research),
All India Institute of Medical Sciences
Ansari Nagar
New Delhi

What will happen to the results of the study?

The results of the project will be shared and discussed with other researchers in scientific conferences (International & National). In the future the results will also be published in the form of scientific papers in reputed journals. We will provide a copy of the findings to the participants of the study, if you desire so. However, the results and findings will be available in journals and online scientific forums for your perusal.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the All India Institute of Medical Sciences Ethics Committee (IEC-745/29.12.2017, RP-19/2018).

What if I want more information about the study?

If you have any questions about any aspect of the study, or your participation in it, not

answered by this participant information sheet, please contact:
Dr. R.K Chadda (Telephone number – 011-26593245)
Dr. Mamta Sood (Telephone number – 01126546634)
Department of Psychiatry, All India Institute of Medical Sciences,
Ansari Nagar, New Delhi -110029

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

About the 'Saksham' App-

- You and your caregiver will be given a Smartphone that has the app 'Saksham' uploaded on it. There are 7 modules in this app, that are medication adherence, daily routine, physical health monitoring, eating healthy, physical activity, self-reliance and psycho-education. Each module has information section that you can read to know more about the particular area that the module is about.
- You will also receive messages or reminders (as set by you) during the week. You can decide what messages or reminders you want to receive during the day.
- Some of these modules require you to enter information related to your medication intake, daily routine and about your physical health status. Investigator or the one of the study team members will explain you how to fill up the information.
- The instructions on how to use this app will be given to you and your caregiver by the investigator, and it is also available in hard copy and soft copy form. If there are any queries or questions, you can ask the investigator anytime during the study.

Please read the following points carefully

- You and your caregiver are required to register with your email id, the first time you use the app. Your email id and password will not be shared with anybody.
- Your name or any other identifying information will not be kept with any of your interactions within the app.
- No one other than you, your families, your doctor and the study investigators, will know whether you and your caregiver are using the app or not.
- The information that you and your caregiver enter or the images taken by you in this app will be kept strictly confidential.
- The app will collect some information from your phone activity, such as the details entered by you in specific app modules and images stored by you in the app.
- Information related to when you opened the documents in this app to read them and when you read the messages shown by the app will be recorded.
- We will not collect any of your location data or record any of your other phone activities beyond what we have described.

- The data collected may be used for research purposes. Again, individual data or personal information (your name, date of birth, address, and phone activity beyond app usage) will not be used on any forum.
- The alarm/ messages that you receive during the day are only for you. These will not be shared with anybody else.
- Your participation is entirely voluntary and you may quit the project at any time. All you have to do tell the study team at AIIMS that you no longer wish to participate and return the smart phone.
- Your participation in this study is independent of your treatment at AIIMS. Your participation in the study will no way impact your treatment.
- This app is NOT a replacement of your ongoing treatment at AIIMS. Please keep consulting his/her treating doctor or therapist.
- If there is an emergency situation, please consult his/her treating doctor or physician.
- We encourage you to think carefully and ask questions from the investigator to clarify your doubts. If there are any questions you may have, please ask the investigator now.

Thank you for taking the time to read this Participant Information Sheet.