About SHARP study

1. The Technology: “mindLAMP”

The LAMP platform represents a patient-centred, transparent, and collaborative approach to digital health. Open-source and customizable, LAMP is a mobile application, dashboard, and digital health platform built with the knowledge that mental illness is as universal as it is personal. Researchers, patients, and care providers can build on LAMP’s software to create, customize, and share digital health tools that meet their needs. **LAMP has already been used in five countries and translated into six languages.**

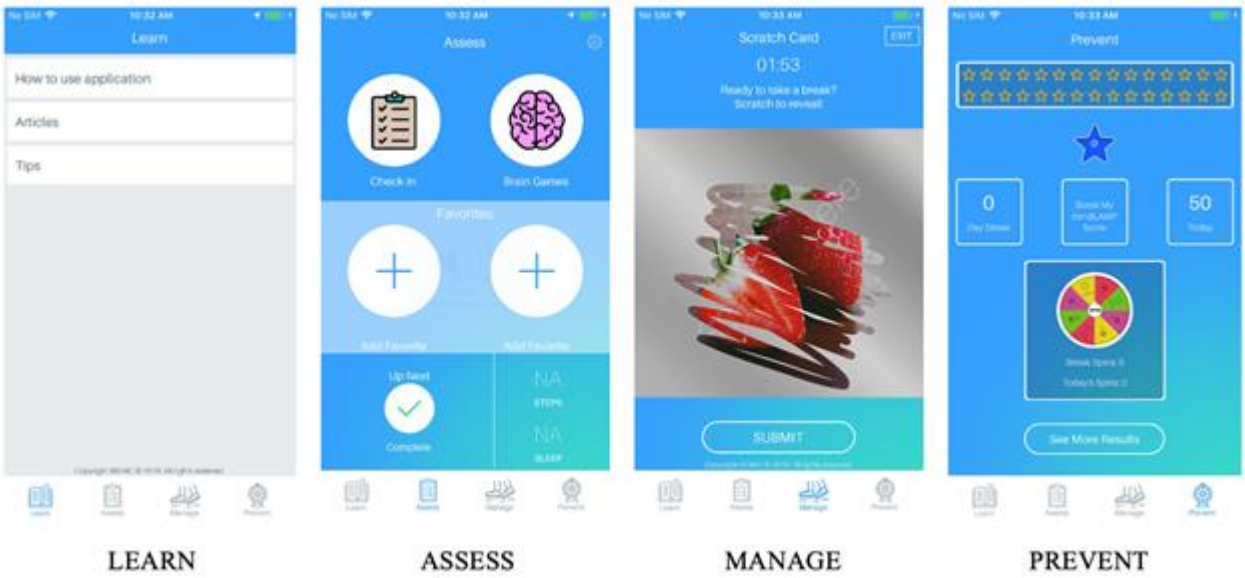

Figure 1: LAMP Is a Customisable Digital Platform That Offers Tools Designed to Help Inform and Supplement Clinical Care

The Digital Psychiatry division at BIDMC designed the LAMP platform through a partnership with the Zco Corporation, a software development company. LAMP consists of **three components:**

i. mindLAMP – a smartphone app that captures surveys, physiological data via Apple HealthKit and Google Fit, passive data, and games that assess cognition. The app can offer tips and mental health on-demand or as triggered by patterns of captured data.

ii. **A dashboard** that aggregates and displays patient data that can be shared with clinicians, family members, and trusted peers.

iii. **A backend secure database**, server, API, and middleware layer to support flexible use cases

The mindLAMP App

The LAMP Dashboard

Figure 2: Core Components Combine to Make LAMP A Data Collection And Visualization Tool

With smartphones increasingly owned and used by patients today, mindLAMP is well-positioned to collect temporally dense and longitudinal data. Through analysing movement via GPS, exercise and sleep via an accelerometer, cognition via on-screen neuropsychological assessments, and symptoms via surveys, mindLAMP captures an integrated record of patients' experiences, cognitive abilities and activities. **An aberration from a patient's baseline data might indicate an early warning for relapse and an opportunity to intervene.**

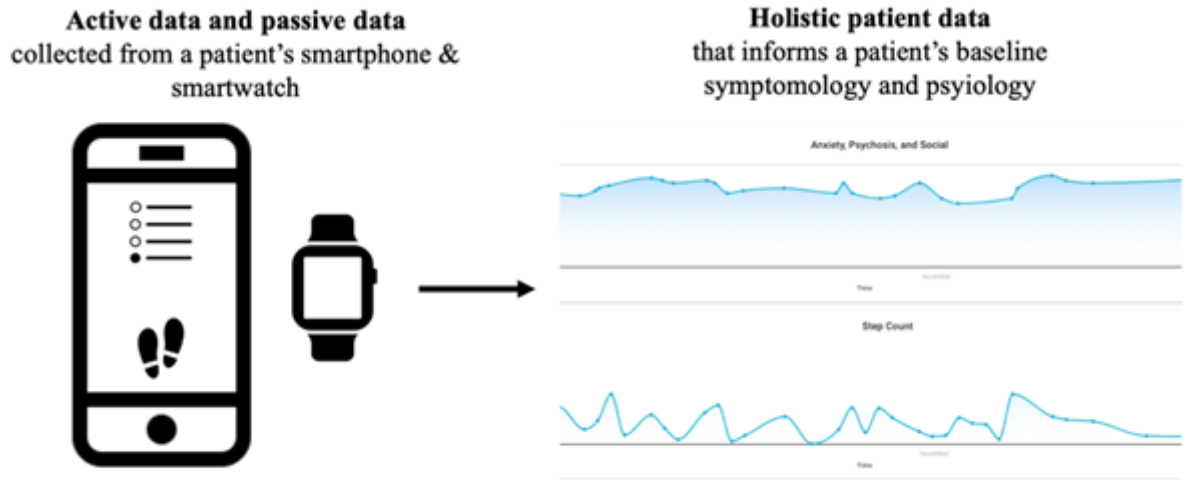

Figure 3: Active and Passive Data Collection Makes It Possible to Detect Abnormal Patient Activity or Mood Fluctuations.

This study will further develop and explore simple activities designed to moderate sudden shifts or drastic changes in a patient's baseline symptomology or physiology. While these app activities are not designed to replace treatment, they are designed to offer in the moment and relevant support and education**. Activities will include resources ranging from psychoeducation tips on sleep to brief breathing exercises.** Further details are tabulated here

2. Study Components

Phase 1 – Qualitative Feedback and mindLAMP Adaptation

The specific aim of phase 1 is to involve patients, family members, and clinicians in co-designing and adapting LAMP to meet their needs and to account for contextual factors specific to each research site. In line with **human-centered design philosophy**, we are interested in understanding how clinicians and patients and their families may want to use the app, especially more about the features, visualizations, and functionality that can make the app most appealing and relevant for use in their daily lives. In this phase, each site (Boston, Bengaluru and Bhopal) will lead focus groups for three subsets of participants (i.e., individuals living with schizophrenia, their family members, and clinicians). Insights from these focus groups will inform modifications to LAMP and the creation of new content tailored to each study setting. Resulting adaptations to the app will be presented back to participants for them to evaluate and test in light of their initial impressions and suggestions. Phase-1 aims to improve usability, functionality, and ensure cultural relevance across sites by engaging users in discussion and developments. **Focus groups** will be separately conducted for patients and their family members, and clinicians, and will include a demonstration of the mindLAMP app, discussion on preferences related to features and functions and a survey on smartphone access and use for participants. The insights across the three sites will be analysed and converted into a technical specification for app improvements. Participants will have the opportunity to test any improvements made to the app and offer additional comments in a follow-up focus group.

Figure 4: *Focus Group Discussions Collect Insights That Inform Adaptions and Updates to The MindLAMP.*

There will be approximately a total of 135 participants recruited for the focus groups in the study. For the patient and family members focus groups, we will recruit a target of n=25 at each site. For clinician focus groups, we will recruit a target of n=20 at each site. All focus groups will be subdivided further into two sections no larger than n=10 to facilitate engagement and encourage active participation. Research staff moderating the sections will be educated around mental illness and will also be made familiar with the LAMP technology. Focus group facilitators will undergo additional training to equip them with interviewing skills and applicable design thinking techniques.

Sample prompts for discussion include:

- *What kind of apps on your phone do you regularly use?*
- *Tell me about a recent time you deleted an app because you found it not usable? Why wasn't it usable?*
- *What do you think makes an app more or less usable?*
- *What information do you like having about yourself?*

mindLAMP Adaptations

Based on the results of phase 1, improvements in functionality, content, and design will be made by Zco over the course of 3 months. Changes to the LAMP will be guided and overseen by the research team at BIDMC to ensure they reflect the insights collected from focus group participants at each study site. In keeping with the study's aim to build a scalable and shareable digital solution, the final code base of the LAMP will be publicly posted online. This will ensure the reproducibility of the research and enable others to build and expand upon LAMP in the future.

Phase 2 – Observational LAMP Study

The specific aim of phase 2 of the study is to **assess the real-world use and effect size of the new and updated LAMP app in both predicting and preventing relapse**. No prior research has measured the effectiveness, usability, or feasibility of a mobile mental health app being used across different contexts, cultures and countries.

At each site, over 12 months, we will recruit a target of 25 patients with schizophrenia (75 participants total). Patients' diagnoses will be confirmed through clinician referrals. Patients with schizophrenia who consent to participate in-person – and meet eligibility criteria for the study including a basic understanding of smartphone functioning and language requirements – will be offered the use of the mindLAMP app and a data-enabled smartwatch device for the duration of the study. Each site will also recruit 25 healthy participants as a control group. The control participants will also be offered a generic version of the mindLAMP app as well as a data-enabled smartwatch to allow active and passive data collection. **A total of 150 participants across all three sites will partake in 5 clinical assessments over the course of the study.** Study visits will help engage participants and capture any significant changes in symptomology and behavior. Clinical measurements collected at each visit will include scales validated and commonly used

internationally: the positive and negative syndrome scale **(PANSS)** for schizophrenia to capture symptoms, the Patient Health Questionnaire **(PHQ-9)** to capture depression, and the Generalized Anxiety Disorder 7 **(GAD-7)** to capture anxiety.

Digital Data Collection and Analysis

Over 12 months (phase-2), the smartwatch device and the mindLAMP app will collect a combination of **active** and **passive** data (Figure-6). Details for further reading are here

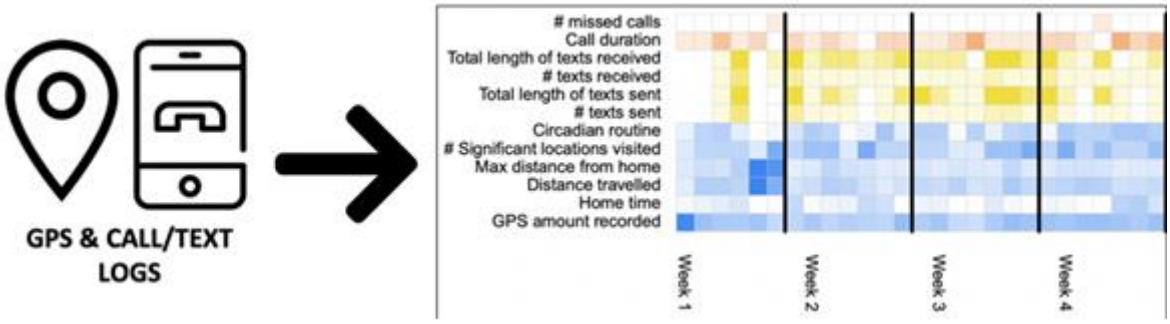

Figure 5: *MindLAMP Protects Privacy by Ensuring That Sensitive Data is De-Identified and Summarized in Aggregate*