Title of research

Telepsychiatry to enable expedited disposition of psychiatric emergencies

Clinicaltrials.gov Registration: NCT05771545

Date of Version: Nov 5, 2021

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Scientific Interest (Key words)		Military psychiatry, Epidemiology, Suicide, Schizophrenia			
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A. English Abstract

Scientific Background: Patients with an acute psychiatric disorder and an indication for involuntary admission are legally required to be examined by a senior psychiatrist. Waiting in the emergency room, until the senior psychiatrist arrives, can be dangerous due to the aggravation of their mental state. In a previous study, we showed that remote video examination is effective and valid compared to face-to-face examination. This strategy has not yet been implemented in practice.

Objectives: 1. Implementation of tele-psychiatry for admission decisions in the emergency department (ED). 2. Implementation of tele-psychiatry prior to being brought to the ED. 3. Evaluation of the effect of these strategies on clinical outcomes and ED utilization.

Working Hypotheses: 1. Remote video psychiatric examination is safe and effective, compared to usual practice. 2. Implementation of telepsychiatry is feasible within the current context, infrastructure, and resources.

Type of Research: Implementation of a novel strategy and comparison with historical controls.

Methods of Data Collection: In the first stage, we will implement remote interviews by senior psychiatrists in the ED, replacing face-to-face interviews. We will measure time spent in the ED, number of violent incidents, and duration of hospitalization. In the second stage, we will implement remote triage by a senior psychiatrist prior to transport to the ED. Patients may be directly admitted, remain at home, or be transported to the ED for further evaluation, based on the findings of the remote examination. At each stage of the study, patient outcomes (n = 60) will be examined over three months and compared to the three months prior to the study (n = 60).

Methods of Data Analysis: We will confirm that groups (pre- and post-implementation) are balanced on measured variables. Assuming they are, we will compare continuous variables (e.g., ED time) using t-tests, and categorical variables using chi-square tests.

Uniqueness or Special Relevance to the National Health Insurance Law: This innovative approach, supported by our preliminary research, has not been tried before. This study has the potential to lead to a system of care that is quite different from current practice and could improve patient safety and well-being.

Possible Policy Recommendations: If our study proves that a remote psychiatric examination is feasible, safe and effective, this approach may be incorporated into official policy. Patients would be able to have an expert, accurate, reliable and fast psychiatrist examination, in the ED or at home. Patients who do not need emergency hospitalization would not be forcibly brought for examination in the ED. Patients who need emergency hospitalization would be able to go directly and safely to an appropriate inpatient ward.

1. **Scientific background:**

   a. *For Patients with Psychiatric Emergencies, The Emergency Department Is an Unsafe Environment*

One of the most extreme interventions that we can undertake in the entire medical profession is to hospitalize a patient involuntarily, for his safety and the safety of others.[1] This is an extraordinary power that is granted to physicians, most often but not exclusively psychiatrists. This represents a grave responsibility, and most physicians take this responsibility extremely seriously and use it only when it is truly warranted. This ability to hospitalize patients involuntarily, until they can be stabilized, undoubtedly allows us to save many lives and keep patients and those around them safer.[1]

While the process of involuntary hospitalization is a very important intervention, it also represents a dangerous time for the patient and those around him.[2] Patients with actue psychiatric decompensation are in an extremely vulnerable state. They may be agitated, may have poor reality-testing, and may be especially dangerous to themselves or others. The very process of transporting them to the emergency department (ED) involuntarily may temporarily exascerbate these risks, although it is part of a process that ultimately results in increased safety.

Patients with psychiatric emergencies can easily decompensate in the ED, sometimes with grave consequences for themselves or others.[3] The ED is a relatively uncomfortable environment that none of us enjoy,[4] but is even more stressful for patients with psychiatric emergencies. This can result, ironically, in the patient's condition worsening, in violent incidents directed toward medical staff, and in starting the hospitalization with precisely the reverse of the intended therapeutic benefit.[3] In general, it is our experience (and the experience of others) that patients with psychiatric emergencies are often calmer, more comfortable, and more secure once they are taken to the psychiatric ward.

In Israel, it is the law that before a patient can be hospitalized involuntarily, he must be evaluated in-person by a senior psychiatrist. The intent of this longstanding policy is to ensure a thorough evaluation before taking the relatively audacious step of hospitalizing a patient involuntarily. However, this policy was created before it was possible to evaluate a patient by video-link. Medical care is increasingly possible via video-link,[5] but Israel's policy of requiring an in-person evaluation by the senior psychiatrist remains in place. Because the senior psychiatrist is often at home, and not already in the hospital, this policy causes the patient to wait in the ED until the psychiatrist arrives. This additional waiting time can increase the opportunities for the

patient to decompensate. We will implement evaluation for involuntary admission via video-link, and measure the impact on patient outcomes.

Our study is premised on the idea that reducing friction for patients with psychiatric emergencies, and reducing irritation when they are least equipped to handle it, will lead to reduced opportunities for decompensation and clinical deterioration.[2] We expect to show that psychiatric ED visits can be shortened, and in many cases, obviated entirely. We expect to show that this approach increases patient safety and promotes quicker resolution of the underlying psychiatric issue.

Many clinical protocols, including those in psychiatry, exist because they have always been done that way, and have never been challenged.[6] These protocols may have developed by chance, or because it was convenient for psysicians, or because of the way hospitals functioned 100 years ago. It is important to reimagine those aspects of medical care that do not have to remain they way they have always been, because they may represent opportunities to improve patient outcomes.[6]

b. Our Group Has Demonstrated that Remote Psychiatric Triage Is Feasible and Valid

In a prospective observational feasibility study,[7] our group evaluated 38 patients with psychiatric emergencies who presented to the ED between April and June 2020. Patients were interviewed by two psychiatrists, one face-to-face, and one via video-link, in varying chronological order. Interviewers and a senior psychiatry resident who observed both interviews determined the diagnosis, recommended disposition, and decided whether involuntary admission was warranted for this patient. Patients and psychiatrists completed acceptability post-assessment surveys.

We compared three pairs of assessments for agreement using Cohen's kappa: between the face-to-face interviewer and the remote interviewer, between the observer and the face-to-face interviewer, and between the observer and the remote interviewer. Agreement between raters on recommended disposition and indication for involuntary admission as measured by kappa was "strong" to "almost perfect", ranging from 0.81 to as high as 0.95 (Figure 1). Partial agreement between the raters on diagnosis was "strong", ranging from 0.81 to 0.85. Psychiatrists' and patients' satisfaction rates, and psychiatrists' perceived certainty rates, were comparably high in both face-to-face and telepsychiatry groups. It is notable that while agreement between psychiatrists was not perfect, especially on precise diagnosis, agreement was <u>not</u> materially affected by interviewing the patient remotely. It is also notable that **agreement on recommended disposition and the need for involuntary admission was especially high**. We

concluded that telepsychiatry is a reliable and acceptable alternative to face-to-face psychiatric assessments in the ED setting.
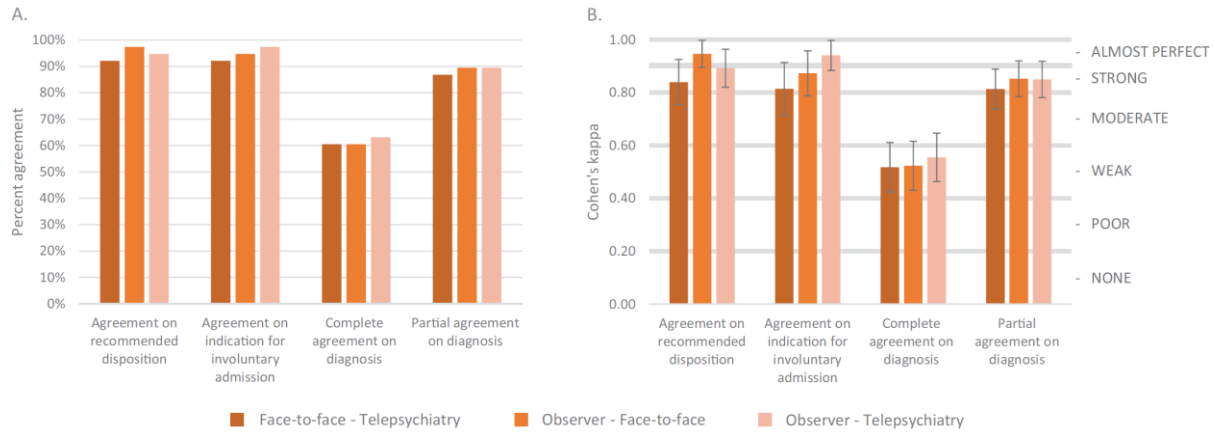

Figure 1: Agreement between raters on recommended disposition, indication for involuntary admission and diagnosis (n=38).

In addition to these measures of agreement, we also measured patients' and providers' satisfaction with the process, as well as providers' level of confidence in their decisions. Patients and providers reported similar levels of satisfaction with remote vs. in-person interviews. Providers reported a similar level of confidence in their clinical decisions with remote vs. in-person interviews.

c. Conceptual Framework and Ethical Analysis

The implementation of virtual triage in the ED is not trivial, but is not especially difficult. The more important issue to consider is why we expect that this strategy will benefit patients, and how we think this will work. This is closely linked to our understanding of the ethical issues involved. Patients with psychiatric emergencies are obviously an extremely vulnerable population. It goes without saying that we should only undertake this project if we expect it to benefit this population directly (and not merely, for example, to reduce ED crowding).

Our assumptions, which will be proven by the success of our project, are discussed above, and are briefly summarized as follows. 1) The ED is not a good place for patients with psychiatric emergencies. It is a place where they decompensate, are unsafe to themselves and others, and receive the opposite of therapeutic benefit.[3] 2) It follows that anything we can do to reduce time spent in the ED will benefit patients. 3) In most cases, psychiatrists are able to decide whether patients require involuntary admission equally well in person or virtually. This is not merely an assumption, but rather something we demonstrated in our previous study.[7] In rare cases where the

psychiatrist remains unsure about whether involuntary admission is needed, in-person evaluation will still be an option.

There could be arguments against virtual triage. However, they are relatively weak arguments. *It could be argued that face-to-face evaluation by a senior psychiatrist will ensure a more thorough evaluation*. Our previous research has disproven this idea.[7] *Second, it could be argued that we should prevent the arbitrary exercise of power by psychiatrists*. However, while we all must be cognizant that such power represents an extraordinary responsibility,[1] psychiatrists are already granted such a power, whether they interview a patient in person or remotely.

Arguments Against Virtual Triage	*Arguments For Virtual Triage*
Ensure adequate evaluation with face-to-face visit	Reduce risk to patients
Prevent arbitrary exercise of power by psychiatrists	Reduce patient discomfort
	Less decompensation contributes to earlier recovery
	Sooner start of therapeutic interventions contributes to earlier recovery
	Some patients may not need to visit ED at all. These patients can avoid the unpleasant experience of being transported to the ED involuntarily

The arguments in favor of virtual triage in the ED are much stronger. We expect that this change will reduce risk to patients, and risk to others, from violent outbursts. We expect that both phases will reduce patient discomfort, distress, and fear. Lessening decompensation by patients in the ED will allow therapeutic strategies to commence earlier, contributing to earlier recovery and earlier hospital discharge.

It is worth noting that our project is defensible on the basis of benefit to patients alone (otherwise, we would not consider it). There are other likely benefits, which do not enter directly into our calculus. This project is likely to reduce ED crowding. Also, this project will save the attending psychiatrist the need to travel to the hospital for most evaluations. We emphatically repeat that while these are indeed benefits, they are not the basis for us performing the study, nor would they be a sufficient reason for this change in policy.

2. **Objectives**

    i.   We will implement tele-psychiatry evaluations in the ED.

    ii. We will evaluate the impact of this strategy on patient outcomes and healthcare utilization, compared to historical controls.

3. **Working Hypotheses**

  a. Remote video psychiatric examination is safe and effective, as measured by clinical outcomes, when compared to usual practice. Patients will spend fewer minutes in the ED, compared with historical controls. There will be fewer violent incidents in the ED. There will not be an increase in the frequency of reversal of involuntary hospitalization, which would imply that a patient was needlessly admitted.

  b. Implementation of telepsychiatry will be feasible within the current context, infrastructure, and resources.

4. **Comprehensive description of study design and methodology:**

Patient Population

    We will recruit study participants from the Jerusalem Mental Health Center, located at Kfar Shaul and Ichilov Medical Center. We will obtain a waiver of informed consent, as this will be a change in standard procedure for all patients for the duration of the study.

    We will include all patients who require an ED interview and an involuntary admission decision by a senior psychiatrist. We will compare patients from the three months prior to the study (approximately 60, based on usual rates of admissions) with patients from the three months of the study (also 60).

    The absence of exclusion criteria will ensure that the study results will be broadly generalizable.

Independent Variables (The Intervention)

    In each study phase, the independent variable will be the study intervention, which will be organized by time. Patients in the pre-intervention period (3 months) will be managed under usual care, and will be the comparison group. Patients in the post-intervention period (3 months) will be managed using the study intervention, and will be the "intervention" group.

Usual care is that patients with psychiatric emergencies are evaluated face-to-face in the ED by a senior psychiatrist for possible involuntary admission. The intervention is that this evaluation will take place via video-link.

Dependent Variables

Dependent Variables

Variable	Type	Data Collection Method
Interobserver Variability	Binary	All video interviews will be recorded. A second senior psychiatrist, blinded to the admission decision, will determine whether admission was warranted based on the recording.
Reversal of Admission	Binary	An involuntary admission which is reversed within 24 hours implies an unnecessary admission. The proportion of admissions reversed within 24 hours will be measured.
Emergency Room Length of Stay	Continuous (minutes)	Measured from the time of arrival in the ED until the patient physically leaves the ED – to go home or to go to the psychiatry ward. Already collected as part of routine practice.
Time from ED arrival to assessment	Continuous (minutes)	We will measure this ourselves, starting with the pre-intervention period. We will measure time until the senior psychiatrist begins his/her face-to-face or virtual assessment.
Violent Incidents in the ED	Binary (any/none)	As recorded by ED staff and adjudicated by blinded review of the chart by a senior psychiatrist.
Patient satisfaction with ED course	Ordinal	We will ask patients to rate their overall satisfaction with their stay in the ED, from 1-5 (very dissatisfied – very satisfied), as they are leaving – starting with the pre-intervention period.
Staff satisfaction with ED flow	Ordinal	We will ask physicians, nurses, and other staff to rate their overall assessment of ED flow, from 1-5, at the end of each month
Duration of hospitalization	Continuous	From the time of entering the ward until the time of leaving the hospital, in hours

Statistical Analyses

We will be comparing the pre-intervention period with the post-intervention period. Above, we have outlined the dependent variables for each phase, and how we will collect them.

We will start by comparing the pre- and post-groups on important baseline characteristics. These will include age, sex, ethnic/social group (Haredi, Arab, General Population), socioeconomic status, and underlying condition (schizophrenia, bipolar disorder, other). We will compare these variables between pre- and post-groups using appropriate bivariate tests (t-test, chi-square). If we find a statistically significant imbalance ($p < 0.05$), we will utilize a multivariable analysis in the main analysis to correct for the imbalanced factors. We do not propose to control for all potential covariates because of limited sample size.

In the main analysis, we will compare the dependent variables explained above between the pre- and post-periods. For continuous variables, we will use an unpaired t-test. For categorical variables, we will use a chi-square test. We will perform two-tailed tests, and will consider $p < 0.05$ to be statistically significant. In the event that we have detected an important between-group imbalance, we will use an appropriate regression model (logistic or generalized linear model), controlling for only the factors that have been found to be unbalanced.

Potential Sources of Bias

A sample size of 60 each in the pre- and post-intervention groups will make it unlikely, but not impossible, that random chance will lead to important between-group imbalance on measured factors. We will assess for such imbalance as part of the analysis plan, as noted above. If there are important differences, we will conduct multivariable analyses to control for a limited number of important unbalanced covariates.

Justification of Sample Size and Study Duration

The study duration is dictated by the maximal duration of a study funded by Machon HaLeumi. The sample size is dictated by the approximate number of patients admitted to our center each month. With 60 patients in the pre-intervention period and 60 in the post-intervention period, we will have statistical power to show a large effect size for some variables, and a moderate effect size for others. For example, if we assume that the average time in the ED is currently

3 ± 1 hours, and that the Phase 1 intervention will reduce this time by one hour, with 60 patients in each group, we would have 80% power to detect such a difference.

It is possible that for some outcomes, our study will suggest the absence of a harm from the novel strategy, but will not be definitive, and that a larger study may be required in the future. However, this concept (triage via tele-psychiatry) is currently not part of standard practice, and even a relatively small feasibility study, powered to exclude important harms, would be an important step forward.

Collection of Implementation Data

We propose to conduct this study as a hybrid implementation study, Type 1. Hybrid implementation studies aim to shorten the process of translating clinical innovations into practice by simultaneously collecting data about the **effectiveness** of the intervention about the **process** of implementing it.[10] A Type 1 hybrid study primarily emphasizes the collection of effectiveness data, but also includes data collection about the implementation process. If the innovation is found to improve care, as we anticipate it will be, collecting data about the implementation process can help inform future efforts to scale up and spread the innovation to other centers (across Israel, and potentially outside it).[10] To this end, we will interview staff who had a role in implementing the intervention in Phase 1 at the conclusion of Phase 1, when their memories of the implementation process are still fresh. At the conclusion of Phase 2, we will do the same. We will interview staff at various levels of the organization, including senior physicians, junior physicians, nurses, other medical staff, and administrators. Some staff members may be interviewed about both phases. Questions will relate to what went well or badly about the implementation process, what factors facilitated or acted as barriers to implementation, and what advice the respondent would give to someone implementing a similar program elsewhere. We will aim to interview at least 12 individuals total for each phase, since this number is usually sufficient to capture the full range of views on a subject.[11] Interviewees will provide consent to be interviewed and to record the interview; those who do not wish to consent will not be included in our study. Interview recordings will be thematically analyzed by our team and will be the subject of a separate report. Participants will not be identified by name in the report.

5.   **Significance:** This innovative approach, supported by the results of our previous research,[7] has not been tried before. We have not found any research reports assessing the impact of such a strategy, nor are we aware of this approach being used in practice inside or outside Israel. Our proposed study has the potential to lead to a system of care that is quite different from current practice, and could improve patient safety and well-being by preventing long waits and thus opportunities for decompensation. We expect to show that this approach allows patients to be put in a safer place much faster, and spend less time in uncontrolled settings. We hypothesize that this will be expressed in fewer violent incidents and shorter hospital stays.

If our study proves that a remote psychiatric examination is feasible, safe and effective, this approach may be incorporated into official policy by the Ministry of Health. Patients would be able to have an expert, accurate, reliable and fast psychiatrist examination. This approach also has great potential to help patients, and health systems, located far from psychiatric specialists. In the Israeli periphery, patients may wait even longer to be assessed than patients who live near population centers, with an even higher risk of decompensation. With a tele-psychiatry approach, a similar level of care could be provided to anyone, regardless of their location.

6. **Resources available to the investigators:**

Dr. Rose is an expert in health services research, implementation science, and medical outcomes research. Dr. Eitan is an expert in psychiatry and telepsychiatry, who has contacts in the world of Israeli psychiatry and with the MOH. They are thus well-suited to co-lead this investigation. Dr. Bistre was lead author on our previous study about the validity and reliability of telepsychiatry;[7] the present study will continue his involvement with this line of research. Dr. Lubin is the manager of inpatient psychiatry at Kfar Shaul, and will oversee day-to-day study operations. The team has the necessary connections with day-to-day operations at Kfar Shaul to ensure that the data will be collected continuously, and the necessary expertise to conduct the study.

Subject confidentiality will be maintained throughout this study, including all publications. Data collected will be safely stored in the research unit of The Jerusalem Mental Health Center. Patients' data will be processed using deidentified serial number. The Research Ethics Committee or other regulatory bodies may receive copies of the study records and may review medical records related to the study.

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