An Innovative Mental Health Virtual Ward: Evaluation of Patient-Centred Outcomes
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Introduction

In response to the changes in healthcare systems delivery accelerated by COVID-19 public health restrictions, novel virtual alternatives to in-person care were launched to support the stabilization of individuals in mental health crisis. In Manitoba, Canada, a Virtual Acute Psychiatric Unit (Castillo et al., 2023) and Virtual Crisis Stabilization Unit (Mental Health Virtual Ward; Pullia et al., 2023) were launched early in the pandemic for residents of Winnipeg (the province's largest city) requiring intensive mental health support, as a strategy to divert need for in-person care in hospital and the community-based Crisis Stabilization Unit. After 2 years, the Virtual psychiatric unit closed due to staffing issues, and the Mental Health Virtual Ward continued to operate at 6-'bed' capacity with Government funding. Effective November 2023, these programs have merged and expanded to the entire province as part of a Provincial Virtual Crisis Service that will offer emergency telemental health assessment to rural health centres and intensive follow-up virtual crisis stabilization support post-crisis visit to individuals across Manitoba. The latter program component is referred to as the Mental Health Virtual Ward (MH vWard) with significant potential to increase access to needed care and provide person-centered alternatives to hospital. As this program is unique, long-term outcomes have not been studied. This research proposes to prospectively measure demographic, recovery, service delivery, and systems use outcomes in a cohort of MH vWard admissions, and 2) to establish a cohort of admissions to use as a historical comparison/baseline for more rigorous evaluation in the future.

Background

There is a Need for Accessible Mental Health Crisis Care in Manitoba. Manitoba has the highest prevalence of any mental disorder compared to other Canadian provinces, with major depressive disorder and suicidal ideation being especially prevalent among Manitobans (Palay et al., 2019). Crisis and emergency systems are common entry points to the mental health systems and serve to support individuals with existing mental health difficulties during times of worsening or increased need (Butler et al., n.d.). Winnipeg emergency departments and urgent care centres receive approximately 10,000 visits for mental health concerns yearly, with nearly half of those at HSC alone (Shared Health, 2018). The Crisis Response Centre – open 24 hours a day for individuals to walk-in and receive mental health assessment and support – has over 6000 annual visits and approximately 17,000 calls to the mobile crisis line (Crisis Response Services, 2022). Depending on the level of need, individuals experiencing mental health crises require intervention options ranging from hospital to community systems. Hospital bed shortages and corresponding long ED wait times to admission (upwards of 40 hours in Manitoba; Canadian Institute for Health Information, 2016) have necessitated alternative solutions for those needing higher intensity support.

The virtual units are modelled after inpatient services based on the concept of a Virtual Ward or Hospital-at-home (Arsenault-Lapierre et al., 2021). Intensive daily care is provided remotely to individuals in their own homes or other place of their choosing. Care is delivered by telephone, email, videoconferencing, and text messaging, with daily on-line live hosted groups offered on a topic related to mental wellness and recovery. After hours support is available through a 24-hour a day crisis line and individuals can also access in person support at the Crisis

Response Centre at any time with continuity of care ensured through use of a common electronic patient record. Although the virtual acute psychiatry unit (staffed by psychiatrists and physician assistants) closed after 2 years due to staffing limitations, the Mental Health Virtual Ward has continued to operate 6 "beds" supported by a multidisciplinary team, with approximately 350 admissions/year, and ongoing high demand despite the in-person CSU returning to full capacity in August 2021. The newly expanded province-wide program is a merging of the virtual units, to have a single 12-bed MH vWard that provides multidisciplinary care from a team of clinicians, nurses, and psychiatrists enabling management of a wide range of patients.

Rationale

Further evaluation needs to determine if this novel service is impacting meaningful outcomes (i.e., recovery, functioning, systems use). While systems level outcomes such as avoided emergency department visits and hospitalization are often prioritized by decision makers and researchers, they may not be the only or most meaningful outcomes for patients and families (dosReis et al, 2022; Frank et al., 2014). For example, in previous work done by the PI on the impact of a post-discharge transitional program for patient with mood and anxiety disorders, it was discovered that many of the components of the planned program either didn't work or didn't matter to patients and families (Bhattacharyya et al, 2015). Identifying the most meaningful outcomes for both the systems and the patients, and evaluating if the MH vWard is having a positive impact on these outcomes is critical to inform ongoing improvement and to make sure that the care is meeting the needs of the people who receive it in the best way possible. We also need to evaluate this program to support ongoing investment in the resources needed to run it, and to support its scale and spread.

Objectives

The objectives of this project are to: (1) prospectively measure demographic, recovery, service delivery, and systems use outcomes in a cohort of MH vWard admissions, and (2) establish this cohort for use in future research.

Methods

Study Design

Objective 1 involves the prospective collection of data from a cohort of MH vWard admissions over approximately 1 year to measure demographic, recovery, service delivery, and systems. Outcomes for consenting individuals will be assessed at time of admission (Time 1), 1 week after discharge (Time 2), 4 weeks after discharge (Time 3), and 6 months after discharge (Time 4). Data on health systems use during the 3 months prior to admission (i.e., pre-test data) and 6 months after admission will be collected in order to identify changes in post-intervention systems use. Within the prospective cohort study, we will also establish the requirements for the cohort to be used for future research (Objective 2).

Patient and Caregiver Advisory Committee (PCAC). This study includes a PCAC who will be involved in the initial selection of outcomes and will give input into the overall study procedures to incorporate the voices of people with lived experience. Given that this study

collects data from individuals experiencing a mental health crisis, the input from a PCAC will be essential to determine optimal data collection protocols that increase recruitment and retention and overall data quality. The PCAC will consist of approximately 6 individuals/caregivers from across Manitoba who have lived experience with crisis services. The PCAC will meet regularly with the study team to achieve project objectives. Oversight of the PCAC will be through our patient engagement lead and partnership with Peer Connections Manitoba.

Exposure to Intervention

Individuals referred to the MH vWard receive an intensive level of daily support that approximates what would be provided through receipt of in-person services but they remain in the community, usually at their own homes or with family/friends. Care in the MH vWard is delivered by any combination of telephone, email, videoconferencing, and text messaging. Individuals have the option of opting in to the use of a web- or app-based tool to complement their care delivery and support self-management. The typical duration of admission is 5 days with flexibility based on individual needs. The program is 'open' 8am to 10pm. All individuals develop an after-hours crisis plan that varies depending where they are located and what the local resources are.

Program components are as follows:

Individual therapy and care planning. Daily 1:1 sessions with a clinician or psychiatry team member to assess and monitor, develop and progress on recovery goals, discuss referrals, etc.

Engagement of formal and informal supports. Direct and indirect communication with community providers for collateral and collaboration, as well as involvement of informal supports (i.e. family, friends) through engagement during 1:1 sessions or additional contacts.

Medication reconciliation and management. Full medication review and reconciliation with program nurse at time of admission. Psychiatry team will manage medications during stay if relevant. Discharge medication reconciliation is completed when appropriate.

Group programming. Daily on-line, live hosted groups are provided for all individuals admitted. These will cover a range of content including skills from Cognitive Behavioural Therapy, medication education, etc.

Referrals for follow-up services. Referrals to community-based services for ongoing support post-discharge.

After hours support. All individuals will create their own individualized after hours support plan at the time of referral and/or intake. Depending where the individual resides this will include crisis lines, in person options, etc.

Telus Home Health Monitoring (HHM) App. At intake, individuals may opt in to using the Telus HHM app which is custom designed to complement the services provided by the program. This system has been approved and adopted by Shared Health for the remote home monitoring of patients. The app pushes periodic surveys to admitted individuals that prompts them to track symptoms and monitor their progress, select availability for 1:1 support and group programming, and work through their crisis plan if needed. The app also allows the custom selection of educational resources that the individual can reference as part of their

treatment plan. Alerts can be sent to the clinical team based on any pre-determined criteria that the team identifies (e.g. a symptom score above a certain threshold). The clinical team has access to a dashboard through which an individual's use of the app is monitored during program hours. Individuals are active on the app for the duration of their admission; after which they retain access to the materials for an additional 30 days but no longer are monitored by the clinical team.

Integration with in-person services. In the case that an admitted individual requires their care to step up to in-person, the MH vWard is integrated with emergency services and inpatient units. Whenever possible, individuals are admitted directly from their home to the inpatient unit to avoid an intermediate emergency visit. If needed due to acute safety or other concerns, local emergency services (911, RCMP) are activated and the team communicates directly with the receiving site to ensure continuity of care.

Participants
Eligibility

All individuals admitted to the virtual ward during the study period are eligible for participation in the study. There are no exclusion criteria.

Sample Size

A sample size calculation was made based on the change score (paired t-test) of the study's primary outcome measure for recovery (WHO-5 Well-being Index). The minimum clinically significant difference for the WHO-5 Well-being Index has been established (Topp et al., 2015). Parameter information for the power calculation was provided by a study that used the WHO-5 Well-Being Index in a psychiatric inpatient population (Newnham et al., 2010). The estimated standard deviation of the change score for the present study was determined to be 4.9 based a standard deviation of 5.5 and a r_{within} of 0.6. Additional parameters included a two-tailed test at α=0.05, a type II error rate of 20%, and a medium to large effective size of 0.65. Based on these parameters, the required sample size is 452.

Drawing on Mental Health Virtual Ward admission statistics in the 2022 calendar year, based on the 6-bed unit, there were about 350 admissions. With the program growing to 12 beds, it is expected the total number of admissions would double to 700 over 1 year. We anticipate about 10-15% of individuals may choose not to participate in the study so we are expecting a sample of around 595 admissions. With participant incentives (gift cards) for responding to surveys and follow up contacts by our team, we hope for an 80% response rate for outcome surveys based on completion rates described by Gilbody et al. (2015) who used a similar method for retention in a trial of an on-line mental health intervention. We estimate that this would result in outcome data at Time 2 for 476 admissions with complete pre and post data over 1 year. Recruitment could be extended by several months if we are failing to meet targets within the 1-year timeframe.

Recruitment
Recruitment script at time of referral & Referral Confirmation/Welcome Email

The recruitment process begins with a welcome email that is sent by the program. From here, interested individuals may click on a link in the referral confirmation/welcome email and self-proceed to review the online consent form and enroll in the study. For those who do not complete this step prior to their admission intake (typically 24-48 hours from receipt of referral), a clinician will follow up to inquire about their interest during this meeting. Those indicating interest at that point will be directed to the same information via email. For those with no email address, permission will be obtained from patients by a clinician for a research team member to reach out for the purposes of discussing the study and enroll over the phone. The first month of the study will be a feasibility period to test out our recruitment strategies. The researchers will seek feedback and suggestions to troubleshoot recruitment barriers from the clinical team members and the PCAC during this time. Recruitment strategies will be adjusted as required.

Data Collection
Data will be collected through self-report surveys at designated time points, as well as chart review to collect service delivery and healthcare utilization data.

Participant Incentives. Participants will be offered honoraria as incentives for study participation. Participants will be offered $5 gift cards at each follow-up data collection time points (Time 2, 3, and 4). Gift cards will be administered electronically (unless physical cards are requested) by the RA.

***Variables* & Data Sources/Measures**
Variables of interest for the study include participant demographics, along with service delivery, recovery, and systems use outcomes.

Demographic Variables (Time 1). The Demographic Questionnaire and SINCERE questionnaire will be completed at Time 1 (admission). The demographic questionnaire will include variables related to sociodemographic information: age, gender, education, income, employment status, relationship status, living situation, urban/rural residence, race/ethnicity, and clinical reason for referral/diagnosis. The data will be collected from participant self-report.

Recovery Outcomes (Time 1, 2, 3, and 4). Recovery will be measured using 2 questionnaires that were co-selected with input from the PCAC: the **WHO-5 Well-Being Index** and the Maryland Assessment of Recovery Scale- 12 item (MARS-12). The Who-5 Well-Being Index is a 5-item measure that assesses subjective psychological well-being" (Topp et al., 2014, p. 167). It has been used to monitor global recovery among psychiatric inpatients showing good sensitivity to change with an established MCID that correlates to other validated measures of psychiatric impairment (Topp et al., 2014). MARS-12 is a shortened version of the MARS-24 designed to measure recovery orientation among individuals with mental illness (Drapalski et al., 2012).
Service Delivery Outcomes (Discharge). Service delivery outcome data are: length of stay, and outcome of stay (discharge, transfer to in person CSU/hospital, emergency activation, and lost

to follow-up. These data will be provided by the clinical team lead as a report approximately monthly.

Systems Use Outcomes (Time 1, 2, 3, 4). Systems use outcomes will include: CRC use, Emergency Department use, and psychiatric hospitalizations. We will collect both self-report and health administrative data to assess for recall bias and to enable some systems use outcomes for individuals who are lost to follow-up in the study. At baseline, systems use in the 3 months prior to admission will be collected. At time 1 and 2, we will collect systems use since discharge from the MH vWard. At time 4, we will collect prior 1-month utilization, including if they utilized the MH vWard again during that time period. Self-report systems variables will be collected using a modified version of the Service Utilization based on the **Client Service Receipt Inventory (CSRI)**. Corresponding health administrative data will be extracted from the electronic medical records of participants by a research team member. Reliable health administrative data will only be available for Winnipeg-based participants as few rural health care facilities utilize the available electronic medical records (most are paper-based).

Time Points
　　　　Data will be collected at 4 different time points:
Time 1 (baseline):
- Participants are to complete baseline questionnaires within 72 hrs of admission
- If a participant does not complete questionnaires within 72 hrs of admission, the participant will be excluded from further data collection.

Time 2 (primary outcome):
- Participants are administered questionnaires 1 week AFTER discharge, with + 1 week of leeway for completion (within 7-14 days of discharge).

Time 3 (secondary outcome):
- Participants are administered questionnaires 5 weeks AFTER discharge, with +/- 1 week of leeway for completion (within 4-6 weeks of discharge).

Time 4 (secondary outcome):
- Participants are administered questionnaires 6 months AFTER discharge, with a +/- 2 weeks of leeway for completion (within 6 months -2 weeks and 6 months +2 weeks).

	Time 1 (admission)	Discharge	Time 2 (1 week post discharge)	Time 3 (5 weeks post discharge)	Time 4 (6 mos post discharge)
Demographic data (Demographic Questionnaire; SINCERE)	X				
Recovery outcomes (WHO-5,	X		X	X	X

MARS-12; Global Recovery Questions)					
Service Delivery outcomes (Data capture sheet)		X			
Systems use outcomes (Service Utilization; data capture sheet)	X		X	X	X

- For self-report surveys at Time 1, 2 and 3, data may be collected through the Telus HHM App as they will also be utilized for assessment and care planning purposes (for those utilizing the App as part of their care), RedCap (for those not utilizing the App), or by phone or in person, for those with this preference or who lack an email/internet connection. All participants will complete questionnaires at Time 4 on REDCap.

Participants completing questionnaires electronically (Telus, REDCap) will receive up to 2 reminders by phone or email at Time 2, 3, and 4, if needed.

Participants completing questionnaires over the phone or in person with the RA will receive up to 2 phone calls to connect for the purpose of completing the questionnaire together.

All data entered into the Telus HHM App for consenting participants will be output in an electronic report by a clinical team member and shared with the research team. The research team member will then manually enter these responses into the REDCap survey.

Data Storage

Clinicians will upload PDF reports containing questionnaire responses generated from the Telus App into a shared folder on the Shared Health Network drive, accessible by the PI. The PI will generate hard copies of the reports for the RA to extract the data from. Once data are manually entered into REDCap and verified, hard copies will be destroyed using confidential shredding. All responses will be stored in REDCap along with identifying data and consent information.

Statistical Analyses

Data collected on the cohort will be quantitatively analyzed using **descriptive statistics** to summarize the baseline characteristics and service delivery outcomes. Change in primary outcome measure (assuming a continuous measure) over time will be assessed with a **repeated measures ANOVA** using a **general linear model** with sociodemographics, clinical variables, and length of stay entered as time-invariant covariates. **Maximum likelihood estimation** will be

used to calculate marginal means at each time point for the same cohort of MH vWard participants. Significant main effects of time will be statistically evaluated. Secondary outcomes will be assessed with similar methods depending on types of variables. Depending on the number of outcomes and relationships between outcomes, **multivariate modelling** may be used.

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