Pilot and Feasibility Studies

STUDY PROTOCOL

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A protocol paper for a pilot randomized controlled trial assessing the feasibility and acceptability of group medical visits for anxiety and depression in adults

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Abstract

Background Group medical visits (GMVs) offer a promising approach to address mental health challenges, particularly in settings with limited access to psychiatric care. Although GMVs have been studied in chronic disease management, their application in mental health, especially through randomized controlled trials (RCTs), remains sparse. This paper describes a study protocol for a pilot study evaluating GMVs as a potential solution to the high demand for mental health services exacerbated by long wait times and resource limitations.

Objectives This protocol paper for a pilot RCT aims to assess whether GMVs will be feasible and acceptable to patients. This pilot RCT will also collect implementation feedback from patients and primary care providers, as well as initial data on clinical outcomes to inform a potential future larger RCT of GMVs for mental health care.

Methods The pilot RCT will enroll 20 participants, randomized to either biweekly GMVs or resumed standard client services. The GMVs will consist of 45-min group sessions and 5-min individual check-ins, facilitated by a psychiatrist for 6 months. Data will be collected on recruitment rates and retention rates, as well as participant satisfaction using the Client Satisfaction Questionnaire-4 (CSQ-4). Clinical outcomes will be measured using the GAD-7, PHQ-9, Mental Health Quality of Life Scale (MHQoL), and Recovery Assessment Scale-24 (RAS-24). Primary care providers will be asked for feedback on their experience with GMVs versus standard client services as well at the end of the intervention.

Discussion This RCT protocol investigates GMVs as a potential solution to alleviate the strain on mental health services, which face long wait times and limited resources. By offering structured group sessions through GMVs, the study aims to enhance access to and quality of mental health care. Designed as an RCT due to limited existing evidence, the study will measure GMV feasibility, patient acceptability, and symptom response. If successful, this pilot study could provide a scalable model to improve accessibility, reduce costs, and enhance patient satisfaction in mental health care, particularly in resource-limited settings.

Trial registration {2A} ClinicalTrials.gov, NCT06651801. Registered 22 October 2024.

Keywords Group medical visits, Mental health, Depression, Anxiety, Feasibility, Acceptability, Randomized control trial

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Administrative information {3}

- The numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers, which have been adapted to a feasibility context and used as a guide when preparing this protocol (for a discussion of adapting the SPIRIT checklist see Thabane and Lancaster [1]).
- The study protocol this paper refers to is version 2, dated March 28, 2025.

Introduction

Background and rationale {6a}

Group medical visits (GMVs) have been introduced and implemented across various settings with the goal of increasing access to medical care, while simultaneously increasing participants' ability to self-manage their illness and connect with peers. GMVs have been studied in areas such as diabetes management, perinatal care, opioid agonist treatment, and pain management [2–5]. In the field of mental health, GMVs have been piloted for feasibility and acceptability to patients in observational settings [6, 7]. However, there have been no studies that have studied GMVs for mental health using a randomized controlled trial (RCT) design. This is of particular importance within the area given the potential confounders with observational data, especially in terms of patient selection into GMVs both from the patient and provider sides.

Currently, in Canada and around the world, the demand for mental health services is very high, leading to long waiting lists, in particular for providers within the public health system. A recent report by the *Fraser Institute* found the average wait time from family physician referral to mental health treatment was 24.7 weeks in 2024 in Canada [8]. Access to psychiatric care is also a significant issue in the USA (for example Sun et al. [9]). Even when patients see their family physician or specialist for mental health assessment, access to treatments can be limited. A study from British Columbia, Canada revealed that in 2016 only 53% of patients with depression receive at least one first-line treatment, whether it be therapy or medication [10]. Related to these issues, there has been much discussion within recent years around family physicians and other primary care providers (PCPs) managing the burden of mental health needs of increasingly complex patients, which was highlighted in a recent editorial in *Canadian Family Physician* [11].

GMVs offer a flexible model of care that can be adapted in various ways but include some key common aspects. These commonalities generally include regular check-ins with participants; assessing for medication benefits and side effects; psychoeducation on mental health and treatment options; and opportunities for mutual support among group members. GMVs can be offered as an alternative to one-on-one psychiatric care in certain contexts. Potential benefits of GMVs for patients include increased psychoeducation regarding diagnosis and treatment options, opportunities for longitudinal diagnostic clarification, and regular scheduled monitoring of medications.

A GMV setting with multiple patients with similar conditions can help increase one's sense of trust and comfort towards providers [12, 13]. GMVs also offer the chance for patients to receive psychoeducational information from providers along with first-hand knowledge from other patients, allowing them to feel more informed and encouraged to use this knowledge when managing their condition [13, 14]. Many of the group therapeutic factors highlighted by Yalom are relevant in the GMV context, in particular imparting information, altruism, universality, and instillation of hope [15]. A group setting consisting of patients experiencing similar challenges can provide a sense of community and reduce feelings of isolation [12, 14]. A major study by Ronald Remick evaluated patients switched from individual psychiatric care to GMVs in British Columbia [7]. Overall, more patients preferred GMVs to individual psychiatric care and in particular reported reduced stigma related to having a mental illness [7].

Another potential benefit to GMVs stems from their value to the health care system. There is traditionally a "mismatch" between demand and supply of mental health services, with long wait lists for care being accompanied by mental health programs not being at full capacity. GMVs may help address these challenges by allowing mental health providers to serve more individuals and connect more people with existing mental health resources. Session nonattendance in mental health treatment sessions is also a significant issue, with various strategies showing evidence to help with this, including prompt appointment scheduling, reminders, and soliciting patient commitment [16]. GMVs offer potential benefits such as regular appointment times and increased commitment from patients due to the group aspect and orientation process, which may help with session nonattendance and capacity issues.

Studying GMVs in a randomized format is important to determine whether they offer additional benefits compared to standard client services, as their implementation requires significant resources and staff training. While initial reports in mental health settings have been promising, they may be influenced by confounding factors. The lack of rigorous evidence supporting the value of Group Medical Visits (or what they call Shared Medical Appointments) is listed as one of the reasons for low uptake among physicians by Ramdas and Darzi in their

2017 paper in *The New England Journal of Medicine* [17]. There are numerous reasons for doing a pilot RCT before a potential larger RCT (for a detailed discussion of these see Lancaster et al. [18]) and ensuring research processes are feasible, the intervention is acceptable to patients, to test data collection procedures, and potentially to inform future sample size calculations.

Study objectives {7}

The primary objective for the study is to evaluate the feasibility and acceptability of study procedures and the GMV intervention. Feasibility outcomes to be measured include recruitment rate and collection of follow-up data. Acceptability outcomes for intervention group participants include retention rates in GMVs and Client Satisfaction Questionnaire-4 (CSQ-4) scores.

Furthermore, preliminary data will be collected on the intervention's effectiveness in reducing depression and anxiety scores, which will guide power calculations for a potential future, larger RCT, as well as implementation feedback from both patients and referring care providers.

The study design follows the CONSORT 2016 extension to randomized pilot and feasibility trials where applicable [19].

Methods

Study design {8 and 6b}

This study consists of a pilot RCT with two arms: an intervention group and a control group. At enrollment, participants will be randomly assigned to either the intervention, consisting of biweekly GMVs for 6 months, or to the control group, which will receive "standard client services". The choice to offer "standard client services" as the comparator group was made to best mimic real-world care in our setting. See Fig. 1 for more information on study flow.

Study setting {9}

This study will be conducted in Winnipeg, Manitoba, where all physician and hospital-based services are publicly funded. Medication coverage is varied and can be through public insurance for low-income or disabled individuals, third party insurers, or out of pocket. In Manitoba, outpatient psychiatric follow-up care for anxiety and depression is generally limited due to long wait times to see psychiatrists. When psychiatrists do see patients with these conditions, they often provide one-time consultations, with recommendations sent back to primary care providers (PCPs). As a result, PCPs tend to

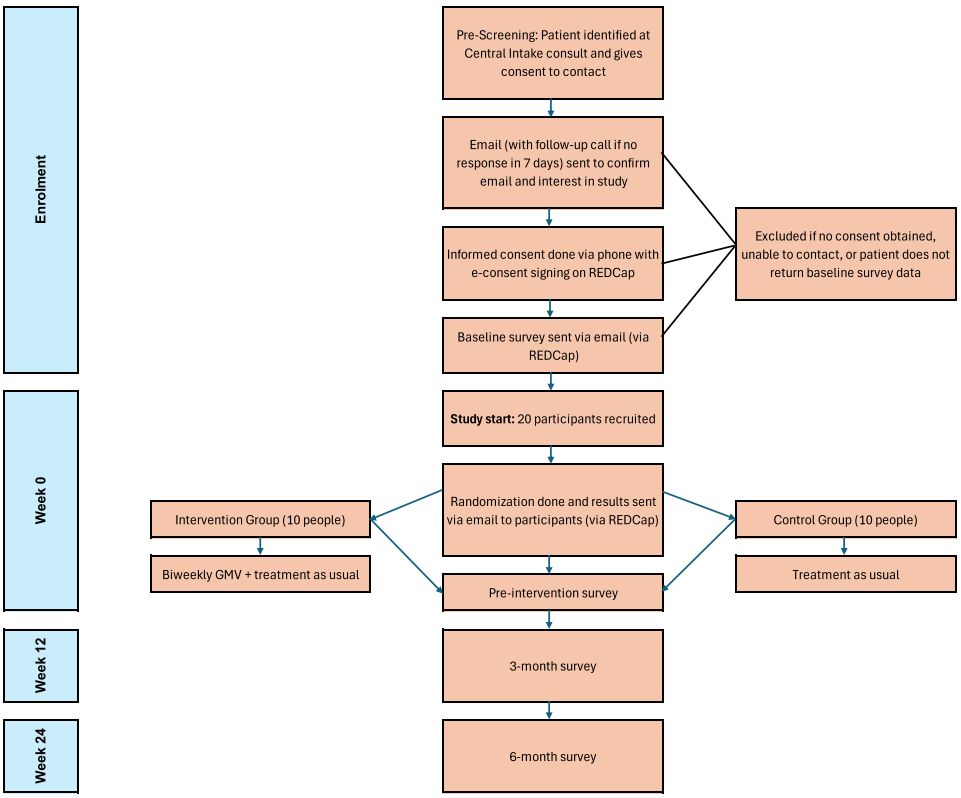

Fig. 1 Study flow

shoulder the responsibility for the ongoing care of anxiety and depression—often managing increasingly complex cases without specialist follow-up. While one-time psychiatric consultations can be effective in some cases, concerns exist regarding the reliability of these assessments, the inconsistent implementation and effectiveness of recommendations, and patients' sense of disconnect from the "mental health system." There is also a parallel private system for psychotherapy, though it remains inaccessible to many due to cost, and often does not include medication management or medical care.

The feasibility of GMVs for psychiatric care in Manitoba and resultant potential for positive impact on patient outcomes has previously been demonstrated in a post-crisis setting [6]. Due to administrative and referral volume challenges, GMVs have since been trialed locally in a less acute general outpatient setting, showing similar uptake and interest among eligible patients. This study will evaluate GMVs in this current context, occurring at Manitoba's largest hospital, the Health Sciences Centre, within the Department of Psychiatry, a tertiary care psychiatric center that offers a range of mental health programs. The Centralized Psychiatry Intake program offers consultation services for patients of PCPs. Currently, follow-up care after Central Intake consultations is inconsistent, with most patients being referred back to their PCP after a one-time consultation. Although group psychotherapy (primarily Cognitive Behavioral Therapy) is available in a timely manner post-consult, access to ongoing psychiatric care is limited. The Department of Psychiatry operates in an academic setting with a multidisciplinary team, including psychiatrists, psychiatry residents, and allied health professionals such as social workers, nurses, and pharmacists.

Participant eligibility {10}

Recruiting will include adult participants (over age 18) who have a Central Intake consult and are interested in further psychiatric care in a group model. Participants who are accepted will have a primary diagnosis of depression (either major depressive disorder or persistent depressive disorder) and/or anxiety (including generalized anxiety disorder, social anxiety disorder, or panic disorder).

Comorbidities can be present. Exclusion criteria include

- Patients suspected or confirmed to have Bipolar Disorder Type 1 or 2 (even if the current episode is depression).
- Primary diagnosis of a personality disorder leading to anxiety/depression symptoms (personality disorder traits are not an exclusion criteria).
- Primary diagnosis of obsessive–compulsive disorder or posttraumatic stress disorder (can be comorbidity if able to participate in groups).
- Concern about the safety of other group members/facilitators if this patient were to join.
- Patients who already have longitudinal care with a psychiatrist.
- Received electroconvulsive therapy (ECT) treatment within the past 6 months.
- Any diagnosis that would significantly impact the ability to participate in the group. For example:
    - Moderate to severe substance use disorders (particularly substance use throughout the day or inability to attend the group without using substances beforehand).
    - Current psychotic symptoms.
    - Moderate to severe intellectual disability or neurocognitive disorder.
    - Current significant eating disorder symptoms (for example, resulting in significant weight loss/malnutrition or that take up a significant part of the day either mentally or physically).
    - Self-harm behavior requiring medical/psychiatric attention or active suicidal ideation/suicide attempts within the past 6 months.

Recruitment and consent {26a, 15}

Twenty participants will be recruited, with ten being randomized to the treatment group and ten to the control group. Consent for the research team to contact via email and/or phone will be conducted by the referring psychiatrist. Consent to participate in the study will be done by the study team. This will include an initial email (followed by a phone call if no response) confirming their ongoing interest and correct email. If they say yes, they will be contacted by phone by our research assistant to do verbal consent with signing using e-consent in the Research Electronic Data Capture (REDCap) application, which is a commonly used software solution used in research [20]. Consent to participate in the study includes consent to participate in the GMV program, consent to inform PCP of participation, and consent to receive email and phone communications for follow-up information. Participation in the study, regardless of group allocation, will not affect participants' ability to participate in other available options for mental health care.

Table 1 SPIRIT schedule of enrolment, interventions, and assessments

	Study period			
	Enrolment	Baseline	Intervention	
Timepoint		Month 0	Month 3	Month 6
Enrolment:				
Intake consultation	X			
Informed consent	X			
Participant screening	X			
Allocation		X		
Interventions:				
Group medical visits			X	X
Care as usual			X	X
Assessments:				
Mental health history	X	X	X	X
Combined GAD-7 and PHQ-9	X	X	X	X
MHQoL	X	X	X	X
RAS-24	X	X	X	X
CSQ-4			X	X
GMV group feedback				X

Sample size {14}

The sample size of 20 individuals was chosen for various reasons, including the clinical experience of the investigators regarding an optimal GMV size, resources and funding available for our study, and norms/guidelines for pilot studies in general (for a discussion of pilot sample sizes see the recent paper by Totton et al. [21]).

Although the sample size for this pilot was set primarily by pragmatic considerations rather than formal hypothesis testing, we calculated the anticipated precision (i.e., width of the 95% confidence intervals) for the main feasibility outcomes. Confidence intervals for proportions were calculated using the Wilson score method to ensure appropriate coverage in small samples. For example, if 70% retention is observed among 20 participants, the 95% CI would be approximately (48%, 85%) (width 37%). For outcomes measured only in the GMV group ($n=10$), a 70% observed proportion corresponds to a 95% CI of approximately (40%, 89%) (width: 49%). For recruitment rate, if 20 participants are enrolled in 4 months (5/month), the 95% CI would be approximately 3.05 to 7.7 participants/month. These wide intervals are typical of pilot studies and emphasize that estimates from this study will primarily be used for feasibility assessment and potentially for planning a future larger trial.

Participant timeline {13}

For an overview of study flow, see Table 1 for the SPIRIT schedule of enrollment, interventions, and assessments.

Allocating and blinding {16a-c; 17a}

Participants will be randomly allocated to groups 1:1 using the REDCap system after enrollment is completed by the project research assistant. Participants and GMV facilitators will not be blinded to groups. Individuals doing data analysis will be blinded to groups. Allocations will be revealed via email to participants.

Study conditions {11a}

Intervention

GMVs will take place biweekly over a 6-month period and will be facilitated by two professionals, including one psychiatrist. Each session will consist of 45 min of group time, followed by individual five-minute appointments with each participant. These appointments will be conducted sequentially, totaling up to 50 min if all 10 participants are present. The group sessions will involve both open-ended discussions and structured psychoeducational topics related to depression and anxiety—similar to traditional psychiatric follow-up appointments. Topics may include non-pharmacological strategies for managing depression and anxiety, as well as dealing with medication side effects. The individual five-minute appointments allow for personalized check-ins regarding medications, prescriptions (if necessary), and any concerns participants may not feel comfortable discussing in a group setting.

All GMVs will be conducted via Zoom, as this is what has previously been done locally. Additionally, hosting sessions via videoconferencing platforms can help overcome time constraints and transportation barriers [22, 23]. Participants are emailed technical onboarding information prior to the start of the GMV. If there are technological challenges preventing a participant from joining the session, a facilitator will contact the participant by phone to troubleshoot. If the participant is still unable to join the session, facilitators will work with the participant to form a plan so that they can join the next session. Group sessions will not be recorded.

Treatment as usual

The "treatment as usual" group will be designated as "standard client services" for outpatients referred by PCPs for psychiatric assessment of anxiety and depression. This typically includes a one-time psychiatric consultation with suggestions for medication management made to PCPs. It also often includes referral to publicly

funded psychotherapy groups (primarily CBT based) that are available for individuals with depression and anxiety, and/or referrals to other treatment programs that may be relevant, such as treatment for substance use disorders or interventional services such as rTMS. At times, psychiatrists may offer some follow-up after their initial assessment; however, this is limited and often not offered for patients with anxiety or depression due to resource limitations.

Concomitant care during the trial {11d}

Participants will be allowed to receive concomitant care throughout the duration of the trial. Concomitant care will be measured at baseline and months 3 and 6. Between-group differences in concomitant care will be analyzed as a secondary outcome, as one of the goals of the GMV is to connect participants to other existing services.

Data collection {18a-b}

Data will be collected via participant self-report at enrollment, baseline, month 3 and month 6 via REDCap. REDCap is a secure virtual platform maintained by the University of Manitoba for research data collection and management. Participants will be prompted to complete these surveys via email, with reminder emails sent if they are not completed. Compensation will be provided to participants for time spent completing surveys using e-gift cards, 25 dollars per survey up to a maximum of 100 dollars.

Clinical data, which are recorded as part of standard clinical care, such as GMV-related clinical notes will be stored with the clinic according to standard hospital protocols.

Data and outcomes {12 and 18a}

Demographic data

Participants' demographic data will only be asked at the start of the study. Demographic data will include participants' age, gender, highest level of education, source of financial support, total household income, marital status, and if they have children.

Psychiatric history

The research team will be inputting information on diagnoses from participants' recent psychiatric consultation at enrollment. We will also ask participants about their history of hospitalizations, suicide attempts, and medication and therapy trials at enrollment, baseline, and months 3 and 6. We will also be collecting data on their concomitant care at the time points (e.g., "Do you have a family physician or nurse practitioner you see regularly for mental health care?"), including follow-up with their PCP.

Acceptability data and implementation feedback from participants

We will be using the CSQ-4 to measure acceptability to patients. The CSQ-4 is a brief, four-item assessment tool designed to measure patient satisfaction with health care services—providing a quick and reliable measure of overall satisfaction with care [24]. This is a measurement tool that was developed and copyrighted by Clifford Attkisson [25]. CSQ-4 scores have been previously studied as a patient satisfaction outcome in an outpatient mental health population [24].

Implementation feedback will be done solely at month 6, and only in the intervention group. We will ask participants to answer a series of structured questions for feedback on the GMV (e.g., "I found the group comfortable to speak and ask questions in") as well as possible mechanisms of benefit (e.g., "I feel more positive about my diagnosis of depression/anxiety after doing the program"). These questions will be rated on a 5-point Likert-type scale, from 1 = strongly disagree to 5 = strongly agree.

Acceptability data and implementation feedback from PCPs

At month 6, all PCPs will be contacted by phone for a semi-structured interview and will be asked a series of open-ended questions around GMV implementation (e.g., "What could we improve about the GMV program from the PCP perspective?") as well as the acceptability of care that their referred patient has received (e.g., "What aspects of care were you satisfied with?").

Clinical outcome data

We plan to examine the following outcomes: Generalized Anxiety Disorder-7 (GAD-7) and Patient Health Questionnaire-9 (PHQ-9) combined, Mental Health Quality of Life (MHQoL) Scale, and Recovery Assessment Scale 24 (RAS-24) at enrollment, baseline, and month 3 and 6 [26–30].

The MHQoL is a recently developed measure designed to assess quality of life specifically in people with mental health problems [28]. It specifically looks to assess an

Table 2 Feasibility and acceptability progression criteria

Outcome	Progression criteria for feasibility/acceptability
Temporal recruitment rate	5 patients/month 20 patients/4 months
Retention in study data collection	70%
Retention in GMV	70%
% of GMV participants who score > 12 on CSQ-4	70%

individual's sense of self-image, independence, mood, relationships, daily activities, physical health, and future.

The RAS-24 is a shorter version of the original 41-item Recovery Assessment Scale, which measures personal recovery in individuals with severe mental illness [29]. It assesses five factors: personal confidence and hope, willingness to ask for help, reliance on others, prevalence and severity of symptoms, and goal and success orientation. The RAS-24 is a widely used tool for assessing recovery outcomes [29, 31, 32].

Statistical methods {20a-c}

The trial will be reported in accordance with the CONSORT 2010 statement extension to pilot and feasibility trials—with an aim to report descriptive statistics for feasibility and acceptability outcomes [19]. Another aim will be to summarize treatment and control group clinical outcomes and implementation feedback to inform a potential larger study. When assessing feasibility and acceptability outcomes, please see Table 2 for progression criteria. These progression criteria were chosen based on clinical relevance in our study context, as well as being in line with other pilot studies (for example, the recent paper published by Pinto et al. [33]). Recruitment and retention rates have traditionally both been difficult to achieve when conducting RCTs in the field of mental health, and frequently do not meet their targets (for a discussion of this issue see Hall et al. [34]).

Statistical analysis will be undertaken at the end of the 6-month intervention period. Feasibility outcomes, such as recruitment rates and follow-up data collection, will be summarized using descriptive statistics. The temporal recruitment rate will be calculated as the number of participants enrolled per month. Recruitment performance will be summarized with descriptive statistics. Follow-up data will be collected by evaluating the percentage of participants who complete the outcome assessments at the 3-month and 6-month marks.

The acceptability outcomes, including the retention rate in GMVs, will be determined by the percentage of enrolled participants who complete the group sessions. Scores from the Client Satisfaction Questionnaire (CSQ-4) will be analyzed using means and standard deviations (SDs). Additionally, response distributions will be summarized using frequencies and percentages.

We will use scores from the GAD-7, PHQ-9, MHQoL, and RAS-24 to estimate effect sizes and calculate 95% CIs to guide future studies. Given that this is a small and unpowered study, the interpretation of the estimated effect sizes will be done with caution.

The pilot study will prioritize feasibility questions. Primary analyses will be conducted on complete-case data. The extent and patterns of missing data will be described (counts and percentages by outcome and time point), and potential implications for feasibility and interpretation will be discussed. Sensitivity to missing data will be addressed qualitatively in the discussion, focusing on potential biases due to missing data and their possible impact on feasibility conclusions. The approach to missing data, including rates and patterns, will be transparently reported in accordance with CONSORT guidelines for pilot and feasibility trials.

For each primary feasibility outcome, the observed proportion or rate will be presented with a corresponding 95% confidence interval to quantify statistical uncertainty and support interpretation of the findings. All analyses will be conducted using R (version 4.2.3).

Feasibility and acceptability results, and how they compare to our predetermined progression criteria, will inform the decision about a future larger trial. This may result in proceeding with a larger trial, proceeding with modifications, or not proceeding at all.

Participant safety and adverse events {22, 27}

There are no anticipated major risks with participation in this study compared to treatment as usual. The main additional risk would be related to personal health information being compromised, either due to participation in the virtual GMV or due to study data collection. To mitigate this, secure hospital or university-based platforms will be used for all virtual care as well as data collection. Additionally, the full research team, or the principal investigator and study coordinator, will meet monthly to discuss study progress and safety.

Given the elevated risk of self-harm and suicide in patients with anxiety and depression, all study participants will be given information on crisis resources at all data collection points. If a participant reports a recent suicide attempt and/or a significant increase in suicidality (i.e., any increase in score to "3" or an increase by more than 1 point in Q9 of PHQ-9) since the last data collection point, the principal investigator and a research assistant will be notified via an automatic email generated by REDCap. The principal investigator will then contact the participant within 2 business days via phone and/or email to provide crisis resources and ask them to follow up with their PCP. If appropriate, the principal investigator will also inform the participant's PCP about the concerns and that the participant has been asked to follow up with them.

If group facilitators are no longer able to conduct the GMV for any unexpected reason, the study would end. The research team will inform participants and offer to meet to further discuss if needed.

Any potential adverse events will be reported to the University of Manitoba and Shared Health per protocols.

Protocol amendments {25}

Amendments to the protocol will be submitted to the Shared Health and University of Manitoba Research Ethics Boards, who will review and approve before implementation. If changes are made to the consent form during the trial, participants will re-consent. The registration on ClinicalTrials.gov will be updated as well.

Access to data {19, 27, 29}

Study recruitment information will be stored in a password protected file on a secure server and only team members involved in consent and screening will be able to access this file. The data collected from participants will be stored on the secure REDCap database, which will only be accessible by the principal investigator and the project research assistant. They will only be accessing the data if needed for safety purposes and to ensure the data is being collected properly. Once data is collected on REDCap, it will be de-identified and stored on a secure server.

Discussion

GMVs are proposed to help alleviate the current burden on mental health services, characterized by long wait times and limited psychiatric resources. The outlined protocol, using a RCT design, aims to investigate the potential improvement of mental health care access and quality by offering structured group sessions through a GMV format.

It is important to design this study as an RCT as thus far there is limited evidence that supports the use of GMVs in mental health. While observational studies have provided important evidence as to the feasibility and acceptability of GMVs, they are also limited by potential significant selection biases. Our protocol's methods emphasize a measurable and quantitative assessment of GMV feasibility, patient acceptability, as well as real-time symptom response for our GMV patients. By targeting recruitment rates, retention, and participant satisfaction, the researchers aim to establish baseline data that will inform future, larger-scale trials that can further bolster the justification for implementing GMVs throughout our mental health care system. Moreover, feedback from both patients and PCPs will further aid in understanding the impact of GMVs on care quality and the practicality of this approach for mental health settings. This focus on stakeholder feedback reflects a holistic approach, ensuring that the intervention aligns with the needs and preferences of both recipients and providers of mental health care.

This pilot study could have important implications for mental health service delivery, especially in resource-constrained systems. If GMVs are shown to be feasible and well-accepted, they could offer a scalable model to improve accessibility, reduce costs, and enhance patient satisfaction. However, the authors note potential limitations, including only having one set of GMV facilitators and one model of care which may limit the generalizability and could impact the results. As an example of this, the decision was made to only offer the GMV as a virtual group, due to clinical experience suggesting this makes attendance more feasible. However, there are notable differences between virtual and face-to-face groups—a recent review highlighted multiple strengths but also weaknesses such as a decreased sense of group connection [35]. If the virtual format were to influence results negatively, this may lead to the conclusion that all GMVs for mental health are not feasible and/or acceptable, which may not be accurate if other models are more effective.

Another anticipated challenge includes participants being unblinded. Specifically, our control group who would receive "treatment as usual" will be aware that they are *not* receiving additional psychiatric follow-up through GMVs. This may impact their self-reported scores on acceptability and clinical outcomes, as well as potentially decreasing survey completion rates. This decision was made to best mimic real-world settings and understand what benefit GMVs offer compared to standard client services. To ensure this is not impacting data analysis, data analysts will be blinded to treatment groups when analyzing the data.

Despite these limitations, the study represents a proactive attempt to address systemic barriers in mental health care and could contribute to broader discussions on optimizing psychiatric services in public health systems, particularly post-COVID-19, as demand for mental health support continues to rise.

Abbreviations

GMV	Group medical visits
RCT	Randomized controlled trial
PCP	Primary care provider
CSQ-4	Client Satisfaction Questionnaire-4
REDCap	Research Electronic Data Capture
GAD-7	Generalized Anxiety Disorder-7
PHQ-9	Patient Health Questionnaire-9
MHQoL	Mental Health Quality of Life
RAS-24	Recovery Assessment Scale 24
SD	Standard deviation

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40814-026-01802-0.

Supplementary Material 1.

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Authors' contributions
Funding acquisition: KPG; study conceptualization and design: KPG, CK, JH, JS, JM, TA; supervision: KPG, JH, JS, JM; writing—original draft preparation: CK; writing—review and editing: CK, JH, JS, JM, TA, KPG, OA. Statistical analysis: OA. All authors approved the final version of the manuscript for publication.

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Data availability
Not applicable.

Declarations

Ethics approval and consent to participate
Ethics approval was received from the *Shared Health Research and Innovation Team* (SH2024-108) as well as the *University of Manitoba Bannatyne Research Ethics Board* (HS26533; H2024:202). Verbal and electronic consent to participate in this study will be obtained from all research participants.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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