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Complete List of Authors:	Urichuk, Liana; Alberta Health Services, Addiction and Mental Health; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Hrabok, Marianne; Alberta Health Services, Addiction and Mental Health; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Hay, Katherine; Alberta Health Services, Addiction and Mental Health Spurvey, Pamela; Alberta Health Services, Addiction and Mental Health Sosdjan, Daniella; Alberta Health Services, Addiction and Mental Health Knox, Michelle; Alberta Health Services, Addiction and Mental Health Fu, Allen; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Surood, Shireen; Alberta Health Services, Addiction and Mental Health; University of Calgary, Faculty of Social Work Brown, Robert; Alberta Health Services, Addiction and Mental Health Coulombe, Jeff; Alberta Health Services, Addiction and Mental Health Kelland, Jill; Alberta Health Services, Addiction and Mental Health Rittenbach, Katherine; Alberta Health Services, Addiction and Mental Health; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Snaterse, Mark; Alberta Health Services, Addiction and Mental Health; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Abba-Aji, Adam; Alberta Health Services, Addiction and Mental Health; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Li, Xin-Min; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Chue, Pierre; Alberta Health Services, Addiction and Mental Health; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Greenshaw, Andrew ; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Agyapong , Vincent; Alberta Health Services, Addiction and Mental Health; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry
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Enhancing peer-support experience for patients discharged from acute psychiatric care: Protocol for a randomized controlled pilot trial

Liana Urichuk[1,2], Marianne Hrabok[1,2], Katherine Hay[1], Pamela Spurvey[1], Daniella Sosdjan[1], Michelle Knox[1], Allen Fu[2], Shireen Surood[1,3], Robert Brown[1], Jeff Coulombe[1], Jill Kelland[1], Katherine Rittenbach[1,2], Mark Snaterse[1,2], Adam Abba-Aji[1,2], Xin-Min Li[2], Pierre Chue[1,2], Andrew J. Greenshaw[2], Vincent I.O. Agyapong[1,2*]

[1]Addiction and Mental Health, Alberta Health Services, Edmonton, AB, Canada

[2]Department of Psychiatry, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, AB, Canada

[3]Faculty of Social Work, University of Calgary, Calgary, AB, Canada

[*]**Corresponding author:**

Vincent Israel Opoku Agyapong

Department of Psychiatry, Faculty of Medicine and Dentistry, University of Alberta

1E1 Walter Mackenzie Health Sciences Centre (WMC), 8440 112 St NW, Edmonton, AB T6G 2B7 Canada Phone: 1 780 215 7771 Fax: 1 780 743 3896 Email: agyapong@ualberta.ca

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ABSTRACT

Introduction: This study will evaluate the effectiveness of an innovative peer support program. The program incorporates leadership training, mentorship, recognition, and reward systems for peer support workers, and supportive/reminder text messaging for patients discharged from acute (hospital) care. We hypothesize that patients enrolled in the peer support system plus daily supportive/reminder text messages condition will achieve superior outcomes in comparison to other groups.

Methods and analysis: This is a prospective, rater-blinded, four arm randomized controlled trial. 180 patients discharged from acute psychiatric care in Edmonton, Alberta, Canada will be randomized to one of four conditions: treatment as usual follow-up care, daily supportive/reminder text messages, enrollment in a peer support system, or enrollment in a peer support system plus daily supportive/reminder text messages. Patients in each group will complete evaluation measures (e.g., recovery, general symptomatology, and functional outcomes) at baseline, six months, and twelve months. Patient service utilization data and clinician rated measures will also be used to gauge patient progress. Patient data will be analyzed using descriptive statistics, repeated measures, and correlational analyses. The peer support worker experience will be captured using qualitative methods.

Ethics and dissemination: The study will be conducted in accordance with the Declaration of Helsinki (Hong Kong Amendment) and Good Clinical Practice (Canadian Guidelines). The study will receive ethical clearance from an approved Health Ethics Research Board and operational approval from our regional health authority prior to proceeding. All participants will provide informed consent prior to study inclusion. The results will be disseminated at several levels, including patients/peer supports, practitioners, academics/researchers, and healthcare organizations.

Registration details: clinicaltrials.gov: NCT03404882

INTRODUCTION

Background and Rationale

Peer support is emotional, social and practical help provided by non-professionals to assist people with sustaining health behaviours[1]. Effective peer support workers share a similar condition as patients, are currently managing their condition effectively, and have received training to provide support[2]. Peer support can be provided to people with either psychological or non-psychological health complaints by peer support workers with 'lived' experience, and the position of peer support worker may include activities such as advocacy, connecting patients with resources, and experiential sharing, among others[3].

Peer support is consistent with the recovery paradigm in mental health[4], and is differentiated from psychiatric models of traditional diagnosis and treatment. The purported mechanisms through which peer support may function[2] are through experiential knowledge sharing, modeling of adaptive coping strategies, social comparison, and enhancing social support. Moreover, peer support may be particularly useful for patients who have difficulty engaging in conventional services[1]. It may be the case that peer support systems can serve as an entry point into the healthcare system for 'hardly reached' individuals and at the very least, serve as a means of providing supportive services for those who would otherwise not engage in treatment. In addition, providing peer support may offer benefits to the peer supporter worker, by enhancing feelings of competence and personal value[2].

Peer support is valued in recovery-oriented models[4]of mental health and is becoming increasingly implemented organizationally (see Myrick and del Vecchio[5]for a discussion). Many studies have reported positive effects of peer support, including lower inpatient service use, better relationships with providers, and increased engagement (for review, see Chinman et al.[6]). However, a recent rigorous evaluation of randomized controlled trials (RCTs)[7]of peer support studies reported that outcomes were generally mixed and often non-significant. In their review, the authors noted a high degree of bias and methodological limitations in the studies they reviewed, and concluded that "peer support programmes should be implemented within the context of high quality research projects wherever possible".

In addition to methodological improvements needed for research on peer support, there is a need to further develop the peer support workforce. Identified areas of development for peer support programs include[8]: how to define "peerness", role clarity and integration with existing systems, credentialing, and workforce development (see also Myrick and del Vecchio[5]). Within our local context, in the province of Alberta, Canada, peer support for patients has been in existence for many years. Anecdotal evidence suggests there is low uptake (i.e., a number of programs employing peer support workers and difficulty recruiting to available positions) and high attrition for peer support worker roles within the province. There has been a drive to develop curricula and organizational infrastructure to formally train and support peer support workers. Administrators who have worked with peer support workers suggest the lack of adequate incentives may contribute to peer support workforce challenges. Similarly, there are often limited incentives for mental health professionals to provide supervision and mentorship for peer support workers.

In summary, the existing literature suggests there is opportunity for innovation in peer support programs, and there is a need for rigorous methodology to better evaluate outcomes from peer support programs. There is also a need to further develop the peer support workforce. The current paper describes a randomized controlled trial that is designed to systematically evaluate a novel peer support model termed the "Edmonton Peer Support System" (EPSS), which incorporates innovative features of service delivery (i.e., an incentive-based model of training, text messaging) and rigorous methodological design to minimize bias and confounds (e.g., comprehensive measures of outcome; methodological design features including longitudinal, prospective, four arm parallel design, and rater-blinding).

One of the innovative features of this study is the incorporation of text messaging. Text messaging is a relatively low cost, high impact, and easily scalable program that uses existing technology, is devoid of geographic barriers, and is easily accessible to end users. There is evidence that supportive text messaging demonstrates positive effects in terms of symptom improvement and patient satisfaction. For example, patients with depression and comorbid alcohol use disorder showed significantly lower

depressive symptoms on standardized self-report than a similar patient group who did not receive messages (large effect size[9]). A second randomized trial demonstrated similar results (Cohen's *d*=0.67[10]). In terms of satisfaction, over 80% of subscribers reported that a texting program improved their mental health[11][12].

There is also evidence that reminder text messaging improves appointment attendance rates. For example, in a systematic review and meta-analysis of eight randomized controlled trials involving 6615 participants[13], the authors found moderate quality evidence from seven studies (5841 participants) that mobile text message reminders improved the rate of attendance at healthcare appointments compared to no reminders [risk ratio (RR) 1.14 (95% confidence interval (CI) 1.03 to 1.26)]. They also found that text messaging reminders were similar to telephone reminders in terms of their effect on attendance rates, yet cost less than telephone reminders.

Another innovative feature of this study is the incorporation of a peer support incentive system. As discussed, the peer support workforce has been identified as an area in need of development[5], including role clarity, integration with healthcare professionals, and credentialing[8]. Specifically, a lack of a "career ladder" or a clear movement within positions of peer support work has been identified[8], with movement possible laterally (but not upward) within many program structures. In this project, peer support workers will participate in an incentive based system that formally recognizes performance. The EPSS is structured as follows:

- Peer support workers are people with 'lived' mental health and substance abuse experience who are at a point in their personal recovery where they consistently demonstrate the ability to share their individual story in a manner that inspires hope and builds relationships with others. Peer support workers who are employed by Alberta Health Services (AHS), our provincial health authority, will be invited to enroll as foundational members of the EPSS.
- Members will be provided with formalized training developed within our health region, involving knowledge training, practice, and ongoing meetings throughout the program to assist peer support workers in adhering to principles consistent with a peer support framework and recovery philosophy and problem-solving concerns or challenges that may arise. Peer support workers will receive clinical support/mentorship from mental health therapists.
- Patient beneficiaries of EPSS will receive supportive face-to-face visits, phone calls, and interactive text message support from their peer support workers. They will also receive reminder text messages for their appointments.
- Patient beneficiaries will be enrolled as associate members of the EPSS and will be provided with training to act as peer support workers when they are at an advanced stage in their recovery. At this time, they can apply for AHS peer support worker roles as available.
- Contributions of peer support workers will be recognized via attainment of different levels of membership (e.g. "star" levels) and certificates of recognition (bearing logos of collaborating institutions) at formal ceremonies. Star-level recognition will be categorized into: Silver Star Memberships (five stars), Gold Star Memberships (ten stars), and Star Fellowships (twenty stars).
- Contributions of mental health therapists towards supporting/mentoring peer support workers will also be recognized through star memberships and certificates at formal ceremonies.

The hope of EPSS is to increase compassion and decrease stigma, foster multi-disciplinary teamwork, incorporate client/caregiver experiences, and strengthen service provider skills and abilities. Our proposed EPSS will provide training for those with mental health challenges that will enable them to contribute to providing compassionate care for mental health patients. This program philosophy is aligned with regional goals relating to improvement of mental health services in our province[14].

Aim and Objectives

The aim of the project is to evaluate the effectiveness of the EPSS. The patient outcomes are organized according to: recovery variables (e.g., recovery, stigma), functional variables (quality of life, employment), symptom variables (psychological symptoms, general outcomes), and service variables (e.g., heath service utilization, cost, satisfaction), as further described in *Methods and Analysis*. Peer support worker outcomes will also be evaluated, including effectiveness, job satisfaction, acceptability, and recovery.

The objectives of the project include:

1. To compare mean changes in recovery, functional outcomes, clinical symptoms, and service variables after six, and 12 months for patients in each of the four arms: treatment as usual follow-up care, daily supportive/reminder text messages, enrollment in a peer support system, or enrollment in a peer support system plus daily supportive/reminder text messages.
2. To assess job satisfaction, acceptability, and recovery of peer support workers at six and 12 months.
3. To assess job satisfaction among mental health therapists offering support and mentorship for peer support workers.

Hypothesis

We hypothesize that patients enrolled in the peer support system plus daily supportive/reminder text messages will achieve superior outcomes compared to other conditions on each outcome measure used. In turn, patients enrolled in peer support only arm and those enrolled in the daily supportive text message only arm will have superior outcomes to those enrolled in the treatment as usual arm.

METHODS AND ANALYSIS

Overview of Study Design, Timeline, and Participant Selection

This will be a longitudinal, prospective, parallel design, four arm, rater-blinded randomized clinical trial with a recruitment period of six months and an observation period of 12 months for each participant. Table 1 provides an overview of the timeline for the project. The research will be carried out in Addiction and Mental Health clinics in a large, socio-demographically diverse[15] city in Western Canada (Edmonton, Alberta).

Patients who are 18 to 65 years of age, able to provide informed written consent, have been diagnosed with a chronic mental health condition, and are ready for discharge from an acute care facility within the Edmonton Zone with community mental health follow-up will be invited to participate. Patients must have a mobile handset capable of receiving text messages. Mobile phones and a call credit of up to 10 dollars monthly will be provided to those who satisfy the inclusion criteria but do not have mobile phones. Patients will be ineligible if they do not meet the above inclusion criteria, if they have an addiction disorder but not a mental health diagnosis, are not capable of reading text messages from a mobile device, or will be out of town during the 12 month follow-up period. Patients are also ineligible if they do not consent to take part in the study.

Table 1
Gantt Chart Timeline

		Year 1				Year 2			
		Start Date-End Date				Start Date-End Date			
Milestone No.	**Milestones**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Milestone 1: Recruiting and training of peer support workers and trainee in psychiatry									
1.1	Advertising and assembling of peer support workers and recruitment of trainee in psychiatry (the latter will support the research/evaluation components of the project).								
1.2	Training of peer support workers and the trainee in psychiatry								
1.3	Writing up a bank supportive text messages in collaboration with service users and mental health therapists								
Milestone 2: The recruitment of study participants									
2.1	Recruitment, baseline assessment, randomization								
2.2	Assignment into one of the three arms of the study								
2.3	Provision of peer support and delivery of supportive text messages to participants in two arms of the study except the usual care group								
Milestone 3: Follow-up assessment of study participants and collection of administrative data									
3.1	Follow-up assessments of individual study participants (Excluding satisfaction surveys)								
3.2	Follow-up satisfaction survey of participants all groups								
3.3	Collection of administrative data related to health services utilization								
Milestone 4: Data compilation, analysis and preparation of reports, publications, and presentations for multi-scale dissemination									
4.1	Data compilation								
4.2	Data analysis								
4.3	Preparation of reports, publications and presentations								

Interventions

Each of the four intervention arms will be randomly assigned. In the text messaging plus peer support condition, patients will be assigned a peer support worker who will visit them during the last week of their inpatient stay to introduce themselves and build rapport before patients are discharged into the community. The peer support workers will visit the participants up to eight times over a six month period. The peer support workers will offer the opportunity for interactive text message support for six months. In addition to peer support, participants in this arm of the study will receive daily supportive text messages from an automated online application and reminder text messages for their community clinic/program appointments.

Patients in the peer support only arm of the study will be assigned a peer support worker before they are discharged (as described above) and will receive up to eight visits over a six month period, in addition to whatever community clinic/program treatment options they are provided.

Patients in the supportive text message only arm of the study will receive daily supportive text messages from an automated online application and reminder text messages for their community clinic/program appointments.

Patients in the control arm of the study will receive the usual follow-up appointment offered to all patients who are discharged from acute care. They may also be offered a range of community clinic/program treatment options. However, they will not receive peer support or supportive/reminder text messages.

Sample Size

Consistent with the idea that this is a pilot study, the research will utilize data that can be elicited from participants who can be enrolled within existing operational resources. The study will therefore be limited to a sample size of 180, with about 45 patients recruited into each arm of the study. Patients transitioning from acute care are vulnerable to insufficient service follow-up post-discharge, and it can reasonably be expected that only a small number of eligible participants will enroll in and complete the study.

Outcomes

Outcome measures and time points are detailed in Tables 2 and 3, and follow from the aim and objectives of the study. All measures (with the exception of patient experience questionnaire, interviews, and data extraction) are objective measures with published information regarding reliability and validity.

Table 2
Patient-Oriented Outcome Measures

	Construct	Tool	Rater	Time Required	Timepoints assessed		
					Baseline	6 months	12 months
Recovery variables	Recovery	Recovery Assessment Scale [16]	Patient	5 min	X	X	X
	Stigma	Perceived Discrimination Scale[17]	Patient	5 min	X	X	X
Functional variable	Quality of Life	WHOQOL-BREF (World Health Organization Quality of Life Brief instrument)[18]	Patient	10 min	X	X	X
	Employment	Employed[1] yes/no	Patient	1 min	X	X	X
Symptom variables	Overall Outcomes	HoNOS (Health of Nations Outcome Scale)[19]	Clinician	5 min	X	X	X
	Overall Symptoms	BASIS-32 (Behavior and Symptom Identification Scale)[20]	Patient	10 min	X	X	X
Service variables	Health utilization	Data extraction and analysis[2]	Researcher	-			X
	Health services cost	Costs of above services	Researcher	-			X
	Patient satisfaction with service	Patient Satisfaction/Experience Questionnaire	Patient	5 min		X	X
			Total Time	**Client** **Clinician**	~30 min ~5 min	~35 min ~5 min	~35 min ~5 min

[1] e.g., paid full time, paid part time, self-employed, paid casual, temporary or contract work, unemployed, volunteering.
[2] e.g., rates of use, inpatient admissions and length of stay, readmissions, completed appointments, Emergency Department presentations, Emergency Medical Services use, community services appointments, crisis and urgent service calls, no show rates.

Table 3
Peer Support Worker-Oriented Outcome Measures

	Construct	Instrument	Rater	Time required	Timepoints assessed		
					Baseline	6 months	12 months
	Effectiveness	Interview (part a)[1]	Researcher with peer support worker	10 min -			X
		Data extraction and analysis, including: number of texts sent, number of visits provided per patient[2]	Researcher			X	X
	Job satisfaction	Interview (part b)[1]	Researcher with peer support worker	5 min		X	X
	Acceptability	Interview (part b)[1]	Researcher with peer support worker	10 min		X	X
	Recovery	Recovery Assessment Scale[16]	Peer support worker	5 min	X	X	X
			Total Time	**Peer Support Worker**	5 min	20 min	30 min

[1] Includes questions regarding: amount of on the job training; frequency and type of activities and support (received and given); perceptions of accountability, empowerment, self-confidence, self-awareness, self-esteem; satisfaction with support received; role clarity; personal well-being; levels of comfort, and team integration.
[2] e.g., number of text messages sent to/received by each patient, number of peer support visits per patient, peer support worked attrition rates (pre- and post-)

The two symptom variables (HoNOS and Basis-32) will be the primary outcomes and all other measures will be secondary outcomes.

Randomization and Blinding

Randomization will be stratified by primary mental health diagnoses (mood or psychotic disorder) using permuted blocks to ensure balance (1:1:1:1) between the four follow-up community treatment groups. The randomization codes will be transmitted by an independent statistician via text message directly to a researcher's password-protected phone line with a secure online backup. This will commence as soon as participants sign the consent forms.

Because it will not be possible for participants to be blinded, treatment allocation will be made explicit to them as soon as randomization is concluded. Outcome assessors will be blinded to treatment group allocation by not involving them in discussions about study participants and not granting them access to the database which contains the randomization code. In addition, study participants will be asked not to reveal their treatment allocation to their assessor. Moreover, these assessors will not be involved in data analysis. To test the success of blinding we will ask the assessor to guess the treatment group for each participant at six and 12 month follow-up. After data collection is complete all data will undergo a blind review for the purposes of finalizing the planned analysis.

Follow-up Assessment

At six and 12 months, a blinded researcher will contact all study participants and assist them in completing a range of assessment tools relating to the primary and secondary outcome measures. At 12 months, data related to each participant's clinic/program attendance rates and utilization of health services

will be compiled from administrative records by the blinded researcher. A researcher will also contact peer supporters and mental health therapists providing support/mentorship for peer support workers at 6 and 12 months to complete exploratory outcome measures.

Statistical Methods

The primary goal of the statistical analysis will be to produce summary descriptive statistics for the longitudinal data, which will provide estimates for future sample size calculations and enable calculation of effect size. Another goal will be to estimate the variability between the results and what has been stated by our hypothesis for the full study to represent a clinically meaningful difference between the intervention and control groups. The data will be analyzed using repeated measures and effect size analyses, and correlational analyses will be completed between measures at each time point. The results of this study will guide the design for a future, more highly powered, study.

ETHICS AND DISSEMINATION

The study will be conducted in accordance with the Declaration of Helsinki (Hong Kong Amendment)[21] and Good Clinical Practice (Canadian Guidelines)[22]. The study will receive ethical clearance from the Health Ethics Research Board of the University of Alberta and operational approval from our regional health authority (Alberta Health Services) prior to proceeding. The study is registered with clinicaltrials.gov**:** NCT03404882**.** All participants will provide informed consent prior to study inclusion.

The results of the study are expected to be available within 21 months of project commencement. We intend to disseminate the research findings at several levels, including patients/peer supports, practitioners, academics/researchers, and healthcare organizations. Patients involved with the research will be invited to help develop key messages arising from the work and help to determine the format and modality for dissemination of findings. We will utilize existing communication channels within our health authority to disseminate findings to clinicians. We will disseminate findings to academics and researchers through peer-reviewed journals and provincial, national and international academic forums.

DISCUSSION

The results of the study will provide important information with respect to: a comprehensive evaluation of outcomes of peer support; comparability of peer support compared to care as usual; impact of a text messaging in addition to care; and impact of a novel, incentive-based peer support training system. The results of the pilot trial will also inform the implementation of a multicenter clinical trial which may be necessary to validate our study findings. Given the increasing implementation of peer support programs within service organizations, the results of this study will be useful for administrators and clinicians who are interested in incorporating peer support services into existing care.

Although this is a pilot trial, the highest quality design was chosen to evaluate the EPSS. We therefore expect that the pilot findings will inform and support administrative decision-making with respect to further scaling and studying the intervention within the province of Alberta and beyond. Thus, we will plan an organizational engagement strategy to advance discussions about feasibility and effectiveness prior to the conclusion of the trial. This will help ensure the findings are a relevant part of decision-making processes in a way that is aligned with study findings as they emerge. This may facilitate planning of a larger study that is endorsed at both leadership and operational levels, so that the potential impact of the intervention can reach patients in a more timely fashion.

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Competing Interests Statement: Dr. Hrabok receives royalties from Oxford University Press. The other authors have nothing to disclose.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	11
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	11
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	11
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	2-5
	6b	Explanation for choice of comparators	7
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7-9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7-9

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7
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	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	9
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9-10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	N/A
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	10
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	10
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	10
Methods: Monitoring			
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	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
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Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
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Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	11
	31b	Authorship eligibility guidelines and any intended use of professional writers	11
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BMJ Open

Enhancing peer-support experience for patients discharged from acute psychiatric care: Protocol for a randomized controlled pilot trial

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Complete List of Authors:	Urichuk, Liana; Alberta Health Services, Addiction and Mental Health; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Hrabok, Marianne; Alberta Health Services, Addiction and Mental Health; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Hay, Katherine; Alberta Health Services, Addiction and Mental Health Spurvey, Pamela; Alberta Health Services, Addiction and Mental Health Sosdjan, Daniella; Alberta Health Services, Addiction and Mental Health Knox, Michelle; Alberta Health Services, Addiction and Mental Health Fu, Allen; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Surood, Shireen; Alberta Health Services, Addiction and Mental Health; University of Calgary, Faculty of Social Work Brown, Robert; Alberta Health Services, Addiction and Mental Health Coulombe, Jeff; Alberta Health Services, Addiction and Mental Health Kelland, Jill; Alberta Health Services, Addiction and Mental Health Rittenbach, Katherine; Alberta Health Services, Addiction and Mental Health; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Snaterse, Mark; Alberta Health Services, Addiction and Mental Health; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Abba-Aji, Adam; Alberta Health Services, Addiction and Mental Health; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Li, Xin-Min; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Chue, Pierre; Alberta Health Services, Addiction and Mental Health; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Greenshaw, Andrew ; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry Agyapong , Vincent; Alberta Health Services, Addiction and Mental Health; University of Alberta Faculty of Medicine and Dentistry, Department of Psychiatry
Primary Subject Heading:	Evidence based practice

Secondary Subject Heading:	Mental health, Addiction
Keywords:	Peer support, supportive text messages, reminder text messages, randomized controlled trial

Note: The following files were submitted by the author for peer review, but cannot be converted to PDF. You must view these files (e.g. movies) online.

Peer_Support_Protocol_for_Publication-Revised.docx

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	11
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	11
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	11
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	2-5
	6b	Explanation for choice of comparators	7
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
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