Protocol for a pilot study of a smart phone assisted problem solving therapy for men who have presented with intentional self-harm to emergency departments

1.0 BACKGROUND AND RATIONALE

We define self-harm as intentional self-poisoning or self-injury; whether or not there is evidence that the act was intended to result in death. In the past the term used was 'attempted suicide'; however, peoples' motives for harming themselves are highly variable. A person may have more than one motive and motivation is hard to assess. In line with usual public policy in health and social care, we use the term 'self-harm' describing a behaviour – avoiding the word 'deliberate' because many service users or consumers dislike its connotations.

In Ontario, the number of people who present to hospital Emergency Departments with self-harm is difficult to accurately assess, but the best estimate is about 30,000 each year [1]. The most common form of self-harm seen in Emergency Departments (around 80% of episodes) is the intentional consumption of an excess of a medicinal or toxic product, whether or not there is evidence that the act was intended to result in death. Injuries, most commonly self-cutting, form 15-20% of episodes [2].

Two-thirds of people attending Emergency Departments because of self-harm are under 35 years of age. They are high users of health and social care services. Self-harm has a strong association with suicide: 7 patients per 1000 (about 1%) die by suicide in the year after attending Emergency Departments with a non-fatal episode (60 times the general population risk), rising to as many as 30 patients per 1000 over the next 15 years [3]. In a recent longitudinal study conducted at the University of Toronto, "all-cause mortality following a first episode of self-poisoning was 1107 per 100,000 person-years… [with] nearly half of all deaths being suicides, accidents or undetermined intent." [4] About a quarter of suicides are preceded by a hospital visit due to non-fatal self-harm in the previous year [5]. It is the major identifiable risk factor for suicide. Mortality from non-suicidal causes is also high, with significantly more than the expected numbers of deaths from natural causes and from accidents [6]. Whilst four of ten people who present with self-harm are men, they form nearly two thirds of suicides after an episode and are far more likely than women to die of premature death from other causes. [6] The premature deaths are greatly over-represented among young people and the life years lost to the community are many.

Repetition of non-fatal self-harm stands at around 20% annually [3] and is associated with much distress and many unresolved interpersonal problems. It is likely that any reduction in repetition of self-harm will be mirrored by a fall in subsequent suicides. The Canadian Association for Suicide Prevention blueprint for a National Suicide Prevention

Strategy has identified those who have presented to hospital with non-fatal self-harm as a high risk target group to reduce suicide.

People attending Emergency Departments after self-harm receive a variable standard of care in Ontario. Many are not assessed for psychological needs, and the little psychological therapy available is not usually covered by OHIP. Local data from hospitals in Ottawa show that only 4 out of 10 men who present with intentional self-harm are seen by a mental health professional. Few are offered an evidence-based treatment aimed at reducing their risk of suicide or repeated self-harm. At present, assessment for self-harm in adults in Ontario is highly variable and there is no standard protocol for therapy. Assessment of suicide risk is currently a Required Operating Practice for Canadian Hospital accreditation; however, individuals identified as at-risk for suicide rarely receive recommended care [7].

Specialist services offer intensive and lengthy treatment for the minority of people who self-harm diagnosed with personality disorders, such as dialectical behavior therapy or mindfulness based therapy. The evidence for the effectiveness of these specialist therapies comes almost entirely from studies in women.

There have been more than 50 randomized controlled trials (RCT's) in self-harm, mostly based on a psychological therapy, on alterations to the administration of care or a combination of these approaches. The published Cochrane review on intervention following self-harm is 15 years old and found only small and methodologically poor trials; although, small trials of problem-solving therapy suggested benefit and concluded that "larger trials are badly needed." [8] A US review of international literature [9] judged trials to be limited by lack of power; although, "trends suggested incremental benefits from some interventions (in particular, problem-solving therapy for patients aged 15 or older)." The 2011 National Institute for Health and Care Excellence (NICE) guideline on management of self-harm (followed by a further NICE search and published update in 2013) found little that is likely to help with routine practice [10]. An alternative to developing new interventions is to optimize treatment as usual, which usually consists of referral for psychiatric or psychological help as well as other health or non-health services. However, neither a systematic review nor a large multicentre study has found a clear relation between the nature and intensity of standard hospital care and subsequent fatal or non-fatal repetition of self-harm [11]. The recent NICE guideline on self-harm stated that "no conclusions could be made regarding psychosocial interventions for reducing repetitions of self-harm," although there was sufficient evidence to recommend "a well conducted RCT."

Dr. Hatcher has published two such large randomized controlled trials comparing problem solving therapy to usual care in New Zealand. The first study found that in people who were presenting with repeat episodes of self-harm to hospital, problem solving therapy decreased the rate of repetition by about a third [12]. The second study

failed to replicate this finding, but the dose (number and length of sessions) of problem solving therapy was lower than the first trial. Both patients and therapists commented that a longer therapy with some booster sessions may be helpful [13]. A third trial in Maori (the indigenous people of New Zealand) found that when added to problem solving therapy, a focus on "sense of belonging" resulted in significantly fewer contacts with Emergency Departments in the year after self-harm compared to usual care [14].

We have received funding for a multicentre cluster randomized trial from the Ontario SPOR support unit (funded by CIHR and the Ontario Ministries of Health and Research and Innovation) comparing the delivery of smart phone assisted problem solving therapy with treatment as usual in men who present with self-harm. The rationale for focusing on men is that most suicides are in men and previous trials have found that providing generic treatments to everyone does not work. The intervention we will offer builds on previous work by trying to extend the range and intensity of therapy. We will do this by supplementing it with a sophisticated smartphone application that has already demonstrated its effectiveness in men with substance abuse disorders. We will be offering an intervention specifically designed for men who self-harm, as they are hard to engage and are more likely than women to have substance abuse problems. However, before proceeding with the full trial, we would like to carry out a pilot study. The purpose of this is to refine the intervention and treatment manual, as well as test the acceptability and feasibility of the intervention to clinicians and patients.

2.0 OBJECTIVE

The pilot study has three aims. The first is to refine a novel intervention using a combination of a smartphone application with best practice psychotherapy for men who have presented to hospital with intentional self-harm. The outcome will be the generation of a revised treatment manual for problem solving therapy that incorporates the use of a smartphone application.

The second aim is to test the intervention's acceptability and practical usability. We will ask clinicians and patients about the acceptability of the intervention and the acceptability of using routine data sources as outcome measures. This will inform methods of recruitment for the larger cluster randomized controlled trial.

The last objective is to assess feasibility of recruitment. To test this we aim to recruit at least half of the men the study team ask to take part in the pilot study. To test feasibility in referring clinicians, our aim is that at least half of men who present with intentional self-harm to the Psychiatric Emergency Services will be approached and have the TOH form allowing contact details to be passed on to researchers completed.

3.0 METHODS

3.1 Participants and Settings:

The participants will be ten English speaking men (aged 18 and over) who present via the Emergency Department (this usually involves the Psychiatric Emergency Services) of The Ottawa Hospital General and Civic Campuses with intentional self-harm. Men must be English speaking, as questionnaires, data collection tools, cognitive and/or psychological tests have only been validated in English. These materials have not yet been translated into French. This pilot will inform a larger scale randomized controlled trial, which will be translated into validated French material by CHESS Mobile Health Inc.

Participating men will have to have access to a smartphone and a data plan. In the full trial, we plan to offer up to 100 participants smartphones with data plans if they do not own a smartphone. Moreover, participants will be excluded from participating in the pilot if they: have cognitive impairments which render them incapable of using a smartphone; are unwilling to return to The Ottawa Hospital General Campus for follow-up appointments; are unwilling to use a smartphone application to facilitate the treatment of self-harm; or in the opinion of the investigator, they are unwilling to consent and are incapable of committing to a 3 month long study.

3.2 Interventions:

The intervention will be a face-to-face psychotherapy based on problem solving therapy combined with a smartphone application, namely CHESS Mobile Health. The problem solving therapy will be offered for six weekly sessions. The intervention will be delivered by Dr. Hatcher, a staff psychiatrist in Consultation-Liaison Psychiatry at The Ottawa Hospital General Campus. This therapy is recommended by NICE for the management of people after self-harm and has been used by Dr. Hatcher in previous randomized trials of treatment in this population and is the standard of care for this population. A description of the therapy and training materials can be found here, www.problemsolvingtherapy@ac.nz. The face-to-face therapy will be supplemented by the CHESS Mobile Health program (http://www.chessmobilehealth.com) – a mobile application which has been tested in a randomized controlled trial in male Veterans in the USA [15] and found to be effective in reducing harmful substance use. The main interface (see Figure) allows for users to Gather, Connect, Discover, and Plan as well as issue an alert when the user is at a high risk of self-harm or suicide.

- The Gather interface provides users with a social network of supporters. (Supports do not need to have the CHESS Mobile Health application). From here, users can create a personalized profile as well as view My Support Team profiles.
- Through the Connect interface, users can message individual members.

- The Discover interface allows users to keep motivated through a variety of methods. Feedback from our team members with lived experience informs us that this is important for the target population.
- The purpose of the Plan interface is to document the progress of the user and to link with the face-to-face therapy.
    - A daily check-in is prompted to the service user to assess their state of well-being.
    - From a central dashboard, clinicians can view their caseload of users' progress and upload custom surveys.
    - The user can also program high-risk zones through the application's GPS. For instance, if a user is likely to binge drink at a specific bar, they can program said bar as a high risk area and a push notification will be sent to the patient when they are within 100 meters of the bar.
    - The link with the face to face therapy is that users will be able to assess their problem solving style, generate problem lists, define problems, set goals and monitor progress using the application. Previously this was done using pen and paper.
- Upon selecting "Beacon," an emergency notification is immediately distributed to alert members of the user's Support Team.

All participants in the study will have full access to the usual mental health services available in Ottawa. This includes in-patient admission, referral to specialist clinics and crisis intervention teams.

Participants will be asked to complete the Patient Health Questionnaire (PHQ-9) either in hardcopy at each session or electronically though the CHESS smartphone application to assess their depressive symptoms and thoughts of self-harm. Participants will also be asked to complete the Generalized Anxiety Disorder (GAD-7), to assess the severity of their anxiety symptoms, through the CHESS Smartphone Application. At the first and sixth session, participants will be asked to complete the Medical Outcomes Survey Short Form (SF-12), a measure of general health, and a quality of life questionnaire (EQ-5D). At the final session, participants will also be asked to complete a questionnaire about their experiences in the study. Specifically, users will be asked to complete a Likert scale which evaluates the user comprehension and practicality of the application, and will be asked to comment on the e-therapy process (see questionnaire in Appendix one). At the end of their participation in the study, they will also be asked to complete a CHESS

Smartphone Application User Satisfaction survey which is administered through the smartphone application. Participants will also be asked after their final session to complete a qualitative interview to examine the process of enrolment into the study, what they found useful in the therapy and what aspects of the therapy could be improved. Participants in the qualitative interviews will be interviewed by a Research Assistant who is independent of the enrolment and therapy process. We will approach all men who took part in the therapy to complete these qualitative interviews. We will ask their permission to audio record the interviews, and we will transcribe the recordings for analysis. A summary of the findings for each participant will be returned to each participant for feedback.

Furthermore, we will invite staff who work in the Emergency Department and Psychiatric Emergency Services at the General and Civic Campuses to complete a qualitative interview describing barriers and opportunities for referring men to the smart phone assisted therapy. We will aim to interview up to six (6) mental health and Emergency Department staff, or until data saturation is reached.

4.0 ANALYSIS

We will use conventional content analysis to analyse the data [16]. Themes will be identified independently by two separate coders.

5.0 OUTCOMES

5.1 Refinement of the intervention:

At the end of the pilot study, we will develop the patient and clinician treatment manuals to incorporate the smartphone application and customize them so they are specific to our target audience. The customized treatment manual will take into account information from user's experiences of the combined therapy, the questionnaires and qualitative interviews.

5.2 Acceptability of the intervention and data collection:

We will ask clinicians and patients about the acceptability of the intervention and the acceptability of using routine data sources as outcome measures. This will inform methods of recruitment for the larger cluster randomized controlled trial. Acceptability will be assessed by a survey of study participants (see Appendix one) and by qualitative interviews. We are aiming for at least two thirds of the participants to rate all questions about comprehension and user practicability as either somewhat agree, agree or strongly agree. Similarly we are aiming for two thirds of the participants to rate the question about acceptability of data collection as somewhat agree, agree or strongly agree.

5.3 Feasibility of recruitment

We will describe the proportion of men who consented to be participants after being approached by the study staff, as well as the proportion of men who present with intentional self-harm who are referred to the study.

References

1. Canadian Institute for Health Information (2011) Health Indicators 2011. Canadian Institute for Health Information,, Ottawa, Ontario

2. Hawton K, Bergen H, Casey D, Simkin S, Palmer B, Cooper J, Kapur N, Horrocks J, House A, Lilley R, Noble R, Owens D (2007) Self-harm in England: a tale of three cities. Multicentre study of self-harm. Social Psychiatry & Psychiatric Epidemiology 42 (7):513-521

3. Owens D, Horrocks J, House A (2002) Fatal and non-fatal repetition of self-harm: Systematic review. British Journal of Psychiatry 181 (3):193-199. doi:10.1192/bjp.181.3.193

4. Finkelstein Y, MacDonald EM, Hollands S, Sivilotti MLA, Hutsn JR, Mamdani MM, Koren G, Juurlink DN (2015) Risk of suicide following deliberate self-poisoning. JAMA Psychiatry 72 (6):570-575

5. Da Cruz D, Pearson A, Saini P, Miles C, While D, Swinson N, Williams A, Shaw J, Appleby L, Kapur N (2011) Emergency department contact prior to suicide in mental health patients. Emergency Medicine Journal 28 (6):467-471. doi:http://dx.doi.org/10.1136/emj.2009.081869

6. Hawton K, Harriss L, Zahl D (2006) Deaths from all causes in a long-term follow-up study of 11,583 deliberate self-harm patients. Psychological Medicine 36 (3):397-405

7. Caterino JM, Sullivan AF, Betz ME, Espinola JA, Miller I, Camargo CA, Jr., Boudreaux ED, Emergency Department Safety A, Follow-up Evaluation I (2013) Evaluating current patterns of assessment for self-harm in emergency departments: a multicenter study. Academic Emergency Medicine 20 (8):807-815. doi:http://dx.doi.org/10.1111/acem.12188

8. Hawton K, Arensman E, Townsend E, Bremner S, Feldman E, Goldney R, Gunnell D, Hazell P, van Heeringen K, House A, Owens D, Sakinofsky I, Traskman-Bendz L (1998) Deliberate self harm: systematic review of efficacy of psychosocial and pharmacological treatments in preventing repetition. BMJ 317 (7156):441-447

9. Hawton K, McKeown S, Day A, Martin P, O'Connor M, Yule J (1987) Evaluation of out-patient counselling compared with general practitioner care following overdoses. Psychological Medicine 17 (3):751-761

10. National Institute for Health and Clinical Excellence (2011) Longer-term care and treatment of self-harm. vol CG133.

11. Carroll R, Metcalfe C, Gunnell D (2014) Hospital management of self-harm patients and risk of repetition: Systematic review and meta-analysis. Journal of Affective Disorders 168:476-483

12. Hatcher S, Sharon C, Parag V, Collins N (2011) Problem solving therapy for people who present to hospital with self-harm: Zelen randomised controlled trial. British Journal of Psychiatry 199:310-316

13. Hatcher S, Sharon C, House A, Collins N, Collings S, Pillai A (2015) The ACCESS study: A Zelen randomised controlled trial of a treatment package including problem solving therapy compared to treatment as usual in people who present to hospital after self-harm. British Journal of Psychiatry 206 (3):229-236

14. Hatcher S, Coupe N, Durie M, Elder H, Tapsell R, Wikiriwhi K, Parag V (2011) Te Ira Tangata: A Zelen randomised controlled trial of a treatment package including problem solving therapy compared to treatment as usual in Maori who present to hospital after self harm. Trials 12 (117). doi:10.1186/1745-6215-12-117

15. Gustafson D, McTavish FM, Chih M-Y, Atwood AK, Johnson RA, Boyle MG, Levy MS, Driscoll H, Chisholm SM, Dillenburg L, Isham A, Shah D (2014) A smartphone application to support recovery from alcoholism: A randomized controlled trial. JAMA Psychiatry 71 (5):566-572

16. Hsiu-Fang H, Shannon SE (2005) Three approaches to qualitative content analysis. Qualitative Health Research 15 (9):1277-1288