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Supportive text messages for patients with alcohol use disorder and a comorbid depression: a protocol for a single-blind randomised controlled aftercare trial

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ABSTRACT

Introduction Alcohol use disorders (AUDs) and mood disorders commonly co-occur, and are associated with a range of negative outcomes for patients. Mobile phone technology has the potential to provide personalised support for such patients and potentially improve outcomes in this difficult-to-treat cohort. The aim of this study is to examine whether receiving supporting SMS text messages, following discharge from an inpatient dual diagnosis treatment programme, has a positive impact on mood and alcohol abstinence in patients with an AUD and a comorbid mood disorder.

Methods and analysis The present study is a single-blind randomised controlled trial. Patients aged 18–70 years who meet the criteria for both alcohol dependency syndrome/alcohol abuse and either major depressive disorder or bipolar disorder according to the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders IV Axis I will be randomised to receive twice-daily supportive SMS text messages for 6 months plus treatment as usual, or treatment as usual alone, and will be followed-up at 3, 6, 9 and 12 months postdischarge. Primary outcome measures will include changes from baseline in cumulative abstinence duration, which will be expressed as the proportion of days abstinent from alcohol in the preceding 90 days, and changes from baseline in Beck Depression Inventory scores.

Ethics and dissemination The trial has received full ethical approval from the St. Patrick's Hospital Research Ethics Committee (protocol 13/14). Results of the trial will be disseminated through peer-reviewed journal articles and at academic conferences.

Trial registration number NCT02404662; Pre-results.

Strengths and limitations of this study

- This is the first large-scale randomised controlled trial to examine the use of SMS text messages in the treatment of comorbid alcohol use disorders and depression.
- Blinded follow-up assessments will be conducted.
- Objective as well as subjective measures of alcohol use will be employed.
- The degree to which the results of this study can be generalised to other contexts may be limited given that this is a single site study.
- An analysis of the differential characteristics between dropouts and completers over time will not be possible as participants who withdraw consent to participate will not be followed-up for subsequent assessments.

INTRODUCTION

Both clinical and epidemiological studies have indicated that alcohol use disorders (AUDs) and mood disorders co-occur at a higher rate than would be expected by chance.[1] For example, studies from the National Epidemiological Survey on Alcohol and Related Conditions (NESARC), a US-based nationally representative dataset, have found more than a twofold increase in the risk of a mood disorder for those with an AUD (2.2 and 2.4 OR for 12 months and lifetime association, respectively).[2 3] Individuals with such comorbidity present a greater challenge to treatment since they tend to have more severe symptoms,[2] greater disability and poorer quality of life[4] than individuals with just an AUD and may pose a greater economic burden to society due to their higher utilisation of treatment services.[4] Among those with an AUD, comorbid depression is associated with an earlier onset of alcohol dependence, higher rates of lifetime drug dependence,[5] worse outcomes among those entering treatment for alcohol and drug problems,[6] higher relapse following AUD treatment among adolescents[7] and adults,[8] greater severity of suicidality in adult psychiatric patients[9] and higher likelihood of suicide attempts[10] and completed suicides.[11] Patients with a

mood disorder who also have an AUD are more likely to consume a large amount of alcohol before attempting suicide, increasing the likelihood that a suicide attempt will be lethal.[12]

This difficult-to-treat group has proven to be potentially responsive to standard interventions. Mobile phone technology has the potential to provide personalised support for patients and improve outcomes for this group of patients.[13] We have previously shown in a pilot trial that compared with patients receiving only standard care, patients who also received supportive SMS text messages received twice per day had significantly improved depressive symptoms and overall functioning scores at the end of a 3-month period. In addition, patients receiving the text messages also showed a trend towards increased cumulative abstinence duration (CAD), that is, greater number of days without alcohol, and fewer average units of alcohol per drinking day compared with patients receiving standard aftercare.[14] However, we noted in this pilot trial that the improvements in mood and abstinence outcomes were not sustained at 6 months follow-up, with most of those in the supportive text message group who used alcohol during the study period doing so for the first time after the supportive text messages had been discontinued at 3 months.[15] The technology was however acceptable for patients and they perceived that the supportive text messages helped them to remain abstinent from alcohol and also to improve on their mental well-being.[16]

Mobile phone-based text messaging has been proven to be helpful in other substance abuse treatment settings. In one study of young adult hazardous drinkers, a cohort of 45 patients discharged from accident and emergency departments in three urban settings were randomised to receive either weekly text messages with drinking assessments and feedback on goal setting or weekly messages with assessments and no feedback. Those who received the text messages with feedback had improved outcomes at 3 months following discharge, equating to an average of 3.4 fewer heavy drinking days in the preceding month and 2.1 fewer alcoholic drinks per drinking day compared with baseline.[17] Apart from improving outcomes for patients with substance abuse, text messaging has also been shown to improve motivation. For example, a study of young people using cannabis found that participants who received text messages reported feeling motivated to reduce their consumption level and to maintain this reduction.[18]

Text messaging has been helpful in other medical settings supporting smoking cessation,[19] reminding general medical patients of scheduled medical appointments[20] and improving compliance with medication.[21] A review of text messaging interventions for health behaviour change[22] found that of 16 randomised controlled trials identified, 10 reported statistically significantly improved outcomes, while the remaining 6 reported differences suggesting positive trends. One advantage of mobile phone technologies is that they can augment the provision of non-critical patient care within the community, reducing the need for hospitalisation, leading to reduced costs and improved patient quality of life.[23] They also facilitate the delivery of a large number of messages at once and can be used to deliver healthcare interventions which are location-independent, broadening the reach of healthcare beyond clinics and hospitals.[24] Mobile devices are now virtually ubiquitous across all age groups, socioeconomic classes and cultures and this significantly increases their potential for use in healthcare and health promotion.

There is great potential for the use of text messaging interventions in psychiatry, however to our knowledge no previous studies have examined the utility of supportive text messages for patients with AUD and a comorbid mood disorder, except for our previous pilot trial.[14 15] Therefore, we sought to expand on the findings of our pilot study and run a full-scale randomised controlled trial exploring the effects of supportive text messages on treatment outcomes in dual diagnosis patients following discharge from an inpatient treatment programme. The aim of this paper is to describe the study protocol of the current study.

Objectives

The primary objective of the study is to assess the impact of supportive text messages on alcohol abstinence indicators and mood symptoms scores in patients with AUD and a comorbid mood disorder discharged from an inpatient dual diagnosis treatment programme. The secondary objective of the study is to examine the perception of patients with AUD and comorbid depression as to the usefulness of supportive text messages with regard to their treatment and recovery.

METHODS AND ANALYSIS

Study design and setting

The study was an assessor-blinded randomised controlled trial. The research was carried out in the Department of Psychiatry, Trinity College Dublin based in St. Patrick's University Hospital (SPUH). This is a 200-bed independent sector university teaching psychiatric hospital and the largest tertiary referral centre for psychiatric inpatients in the Republic of Ireland. Patients were recruited from those attending and completing an in-patient dual diagnosis or alcohol and chemical dependency programme. The 4-week dual diagnosis and alcohol and chemical dependency programmes consisted of lectures, video sessions, individual and group therapy sessions modelled on interpersonal supportive therapy and recovery planning.[25] All patients were also offered an outpatient aftercare programme. For the first 3 months, patients attended a support group facilitated by an addiction counsellor once a week for half a day. Following this, they attended a support group one evening per week for up to a year. At each follow-up assessment, it was recorded whether the patients in each group were attending aftercare, and in this way any potential group differences associated with aftercare attendance was accounted for.

In a previous study by our group,[14] there were equal number of patients in the text message and control groups attending aftercare (intervention: 37.5%, control: 38.5%, p=1.00), thus any group differences in outcomes were unlikely to be related to attendance of these sessions.

Participants

Inclusion and exclusion criteria

Patients were eligible to be included in the study if they met the following criteria: (1) they were aged over 18 years and were able to provide written informed consent; (2) they had a Mini Mental State Examination (MMSE)[26] score >25 at baseline assessment; (3) they currently fulfilled the criteria for both alcohol dependence and alcohol abuse, and either major depressive disorder or bipolar disorder as assessed using the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV (SCID-DSM-IV)[27] administered by a trained postgraduate qualified psychologist; (4) they were enrolled on the inpatient dual diagnosis or alcohol chemical dependency treatment programmes at SPUH; (5) they had a mobile phone and were familiar with SMS text messaging and were willing to take part in the study.

For patients with major depressive disorder, a score of ≥14 on the Beck Depression Inventory (BDI)[28] at baseline was employed as an inclusion criteria, which indicated at least a mild depressive episode in the past 2 weeks. Patients with an established diagnosis of a comorbid personality disorder and/or anxiety disorder were eligible for inclusion, as were patients with a comorbid substance use disorder, provided that the primary substance use disorder was alcohol dependence. Comorbid disorders were recorded and controlled for in the statistical analyses.

Patients were excluded from the study if: (1) they did not consent to take part in the study; (2) they did not have a mobile phone or were unable to use SMS text messaging technology; (3) they were unavailable for follow-up during the study period; (4) they had a psychotic disorder.

Methods

Recruitment

Potentially eligible participants were identified by the research team through participation in weekly multidisciplinary team meetings at SPUH. These patients were approached by a member of the research team who provided brief details of the study along with an information sheet written in plain English describing the study and what would be asked of them should they wish to participate. If the patients indicated that they were interested in participating, an initial appointment with a member of the research team was arranged during which further details of the study were discussed and written informed consent to participate was obtained after which their eligibility for inclusion in the study was assessed. The SCID-DSM-IV[27] was used to confirm a diagnosis of major depressive/bipolar disorder and alcohol dependence. Cognitive functioning was assessed using the MMSE.[26] All assessments were conducted by a trained postgraduate qualified psychologist.

Baseline assessment

DSM-IV diagnoses and cognitive functioning at baseline were confirmed using the SCID-DSM-IV[27] and MMSE.[26] Level of alcohol misuse difficulty was assessed using the Time-Line Follow Back (TLFB),[29] in which the quantity of alcohol consumed and number of drinking days during the 90 days preceding admission were recorded; the Obsessive Compulsive Drinking Scale (OCDS),[30] which is a self-report questionnaire measuring obsessional thoughts and compulsive behaviours related to alcohol; the Alcohol Abstinence Self-Efficacy Scale (AASES),[31] which evaluates both temptation to drink and confidence to abstain and the Alcohol Expectancy Questionnaire,[32] which assesses alcohol reinforcement expectancies. In order to corroborate self-reported levels of alcohol consumption, blood tests of mean corpuscular volume (MCV), alkaline phosphatase (AST) and gamma glutamyl transferase (GGT), all of which are indicators of alcohol misuse, were conducted at baseline.

Mood-related difficulties were assessed using the BDI-II,[28] which evaluates subjective severity of depressive symptoms; the Beck Anxiety Inventory (BAI),[33] which assesses subjective severity of anxiety symptoms; the Perceived Stress Scale,[34] which evaluates the degree to which life situations are perceived as stressful and the assessor-reported Young Mania Rating Scale (YMRS),[35] which quantifies the presence of manic symptoms. The BDI-II was readministered immediately prior to inpatient discharge to account for subjective changes in depressive symptoms subsequent to completing the inpatient dual diagnosis programme.

Social, occupational and psychological functioning were assessed using the assessor-completed Global Assessment of Functioning (GAF)[36] scale.

Demographic and clinically relevant data were be collected as part of the baseline assessment such as marital, employment and educational status, medical and psychiatric history, concurrent use of psychiatric medication, alcohol misuse and treatment history and family history of alcohol misuse difficulties.

Randomisation and allocation

Prior to their discharge from SPUH, patients were randomised into one of two groups, namely, 'an intervention group' or a 'non-intervention group'. Simple random allocation using a random number generator was conducted by the Research Director in order to ensure allocation concealment. The researcher who assigned patients to groups and sent text messages was not involved in the outcome assessments. As participants were aware of whether or not they were receiving supportive text messages, blinding of patients to their allocated experimental condition was not possible. However, allocation was concealed from outcome assessors. To ensure this, during their baseline assessment appointment, all participants in the study were asked not to reveal

Table 1 Examples of alcohol abstinence and depression-related text messages

Alcohol abstinence text messages	Depression-related text messages
[[[NO ENTITY]]] If certain people, places or activities trigger a craving for alcohol, try to avoid them.	[[[NO ENTITY]]] Remember to be gentle with yourself. You are doing the best that you can.
[[[NO ENTITY]]] If you find yourself recalling the enjoyable aspects of your drinking, remind yourself of the consequences too.	[[[NO ENTITY]]] Your thoughts affect how you feel. Thoughts are not facts. Notice them and watch them come and go.
[[[NO ENTITY]]] Finding activities that do not involve alcohol is vital in recovery. Can you get involved in your community or try a new activity this week?	[[[NO ENTITY]]] Writing can be a useful tool in recovery. Problems can seem more manageable when they are written down rather than just floating around in our head.
[[[NO ENTITY]]] Take it 1 day at a time; recovery is a process, not a destination.	[[[NO ENTITY]]] For today, focus on only what is happening now. Do not entertain negative words, thoughts or actions.
[[[NO ENTITY]]] Without alcohol you have more time and energy for the people and activities that you care about.	[[[NO ENTITY]]] By taking care of our physical health, our past hurts and our present-day stresses we can overcome low mood.

the group to which they were allocated to their assessor during subsequent follow-up appointments. Outside the assessments, outcome assessors were shielded from the accessing of data sources or the discussion of participants in study in forums where the possibility of determining the allocation group of participants could be determined. To assess the success of blinding, assessors were asked to guess the allocation group for each participant at follow-up assessment points. These assessors were not involved in data analysis.

Intervention protocol

Patients in the intervention group received supportive text messages twice per day for 6 months following discharge from SPUH. The messages were sent by a computer programme at 10:00 and 19:00 hours each day and were set up and monitored by the Research Director. Each day patients received one message targeting mood difficulties and another message targeting abstinence from alcohol in accordance with the primary aim of our study (table 1). Text message content was written in collaboration with the research team and addiction counsellors at SPUH and was based on existing aphorisms in the recovery literature. In addition to the intervention text messages, participants in this group also received a biweekly SMS text message thanking them for their participation in the study. Patients in the intervention group also received a fortnightly phone call from the Research Director to confirm that their mobile phone was still operational and that they had received their allocated text messages.

Patients in the non-intervention group received a biweekly SMS text message thanking them for their participation in the study for 6 months following discharge from SPUH as well as a fortnightly phone call from the Research Director to confirm that their mobile phone was still operational and that they had received their allocated text messages. As both the intervention and non-intervention groups received fortnightly calls, any group differences in outcomes were not attributable to the receipt of the calls.

Follow-up assessments

Participants were, at 3-month, 6-month, 9-month and 12-month follow-up intervals, contacted by a blinded researcher and were invited to complete a face-to-face assessment involving the administration of the BDI,[28] BAI,[33] AASES,[31] GAF,[36] TLFB[29] and YMRS.[35] Follow-up blood tests including MCV, AST and GGT were also conducted by an independent phlebotomist. Patients were also asked to report on any adverse events experienced between assessments. At 6-month follow-up, participants in both groups completed a questionnaire assessing their perceptions of their overall treatment programme. Participants in the intervention group additionally completed a questionnaire assessing their perceived usefulness of the SMS messages that they received (figure 1).

Discontinuations

Patients were discontinued from the study if they withdrew consent to participate. These participants were treated as dropouts. If dropout occurred during the intervention phase of the study, delivery of SMS messages was discontinued from the date on which the participant withdrew consent to participate. These participants were additionally not contacted for any periodic assessments in the future.

Outcome measures

Primary outcome

- Cumulative abstinence duration (CAD), which was expressed as the proportion of days abstinent from alcohol in the preceding 90 days as measured using the TLFB.[29]
- 3-Month, 6-month, 9-month and 12-month changes in BDI[28] scores from baseline.

Secondary outcomes

- Proportion of patients continuously abstinent from alcohol at 6 and 12 months.
- Time to first drink following discharge.

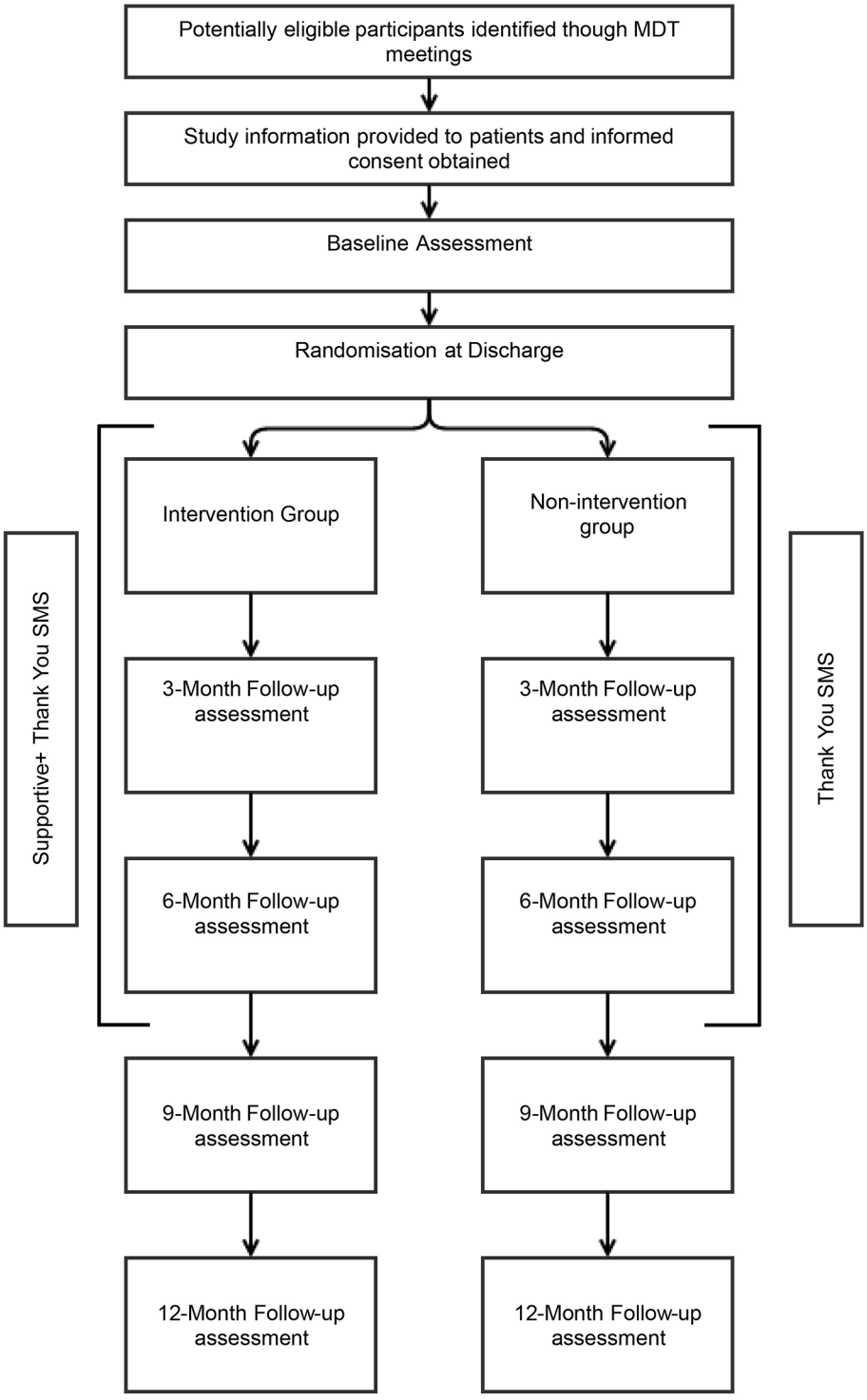

Figure 1 Participant flow through the trial. MDT, multi-disciplinary team.

- 3-Month, 6-month, 9-month and 12-month changes in GGT, AST and MCV from baseline.
- 3-Month, 6-month, 9-month and 12-month changes in OCDS,[30] AASES,[31] BAI[33] and GAF[36] scores from baseline.
- Patient perceptions as to the usefulness of SMS text message technology in supporting recovery (intervention group only).
- Patient satisfaction with their overall treatment protocol (intervention and non-intervention group).

Sample size estimation

Our pilot trial detected a difference of 9 days in CAD between the two groups in the expected direction (88.29 in the intervention group compared with 79.31 in the control group).[14] This difference was not significant, likely because the trial was underpowered. Sample size for this trial was calculated using the online script available at http://www.stat.ubc.ca/~rollin/stats/ssize/n2.html, using the change detected in CAD derived from the pilot trial. Comparing the means of the two independent

samples (ie, 88.29 and 79.31), with a common SD of 17.91 for a two-sided test (ie, not knowing the direction of the change, better or worse, after the trial) for the usual values of alpha=0.05 and power=0.80, the sample size necessary for one group to detect a statistically significant difference would be 63. This equates to 126 participants in total. We assumed a dropout rate of 24% at 1-year follow-up, which is twice the dropout rate of 12% at 6 months achieved in our pilot trial. Thus, a total of 166 subjects would need to be recruited to ensure a sample size of 126. This retention rate is based on our pilot data and on the retention rates we were able to achieve in other studies. In a previous longitudinal investigation, 87.4% and 75.1% of depressed and bipolar alcoholics were successfully followed-up at 6 months and 2 years postdischarge from our inpatient dual diagnosis programme, respectively,[25] the programme from which we recruited for the present study.

Statistical analyses

The first step of the statistical analysis involved the screening and cleaning of the dataset to check for outliers and errors, and following this the data distributions were examined in order to ensure that the assumptions of the statistical analyses were not violated. The demographic and clinical characteristics of the two groups gathered at baseline were analysed using t-test or Mann-Whitney U test for categorical variables, and chi-squared test for continuous variables. The principal analytic strategy for analysing the effects of the intervention on changes in the primary and secondary outcomes over time was multilevel modelling. This is considered a more powerful technique than the repeated-measures analysis of variance or analysis of covariance as it uses all available data, can properly account for correlation between repeated measurements on the same subject, has greater flexibility to model time effects and can handle missing data more appropriately.[37] This analysis requires the assumption that data are missing at random. That is, the probability of non-responding depends only on a participant's observed characteristics.[37] Moreover, in view of our previous finding of better outcomes for depressed and bipolar females at 2 years follow-up compared with male, gender differences in treatment effects is also explored. Descriptive statistics was used to describe the outcome measure relating to patients perceptions as to the usefulness of the supportive text messages. All data were analysed on an intent-to-treat basis with last observation carried forward used to impute missing data using IBM SPSS Statistics for Windows V.24.[38]

Data collection and management

In order to maintain the robust execution of the trial, the following measures were followed: (1) a standardised operating manual for data collection and storage was created and employed by the research team; (2) weekly meetings were held between the research team in order to discuss matters relating to the trial; (3) all research staff received full training by the Principal Investigator (a consultant psychiatrist) on the administration of trial assessment instruments.

Data storage

Data were collected via hardcopy standardised forms and transferred into a computerised database. Electronic records were stored securely in password-protected files on the SPUH file server. Only members of the research team had access to these files. With respect to hardcopy files, these were stored in a locked cabinet within a secure building to which access was restricted to hospital personnel via security fob. Furthermore, the room in which the locked cabinet was located was protected by secure individual key. Only members of the research team were permitted access to room or cabinet keys. All data pertaining to the trial were destroyed by the Principal Investigator 1 year after the completion of data analysis and publication of results.

Study monitoring

Trial steering and data management committees were established. Both committees comprised the Principal Investigator, co-investigators, research workers, a representative of the Hospital's Board of Governors, a service user representative and a member external to the hospital. An independent statistician additionally formed part of the membership of the data management committee. Both committees met to discuss issues relevant to their remit on at least a 6-monthly basis.

Ethical considerations

The study received full ethical approval from the St. Patrick's University Hospital Research Ethics Committee (protocol reference 13/14). The trial was registered at clinicaltrials.gov (reference no. NCT02404662). Informed consent was obtained from each participant via an informed consent form prior to enrolment. The trial was conducted in compliance with the Declaration of Helsinki (Hong Kong Amendment) and Good Clinical Practice (European Guidelines).

Dissemination

The results of the study were presented at several research conferences. It is also anticipated that, due to the size and richness of the database which was created, several articles were published in high impact peer-reviewed journals. All results were reported in line with consolidated standards of reporting trials (CONSORT)[39] guidelines.

DISCUSSION

This study aims to assess the effect of supportive SMS text messaging on mood and alcohol abstinence in patients with depression and comorbid AUD following discharge from an inpatient dual diagnosis treatment programme. While there is good evidence to support the effectiveness of SMS text messaging in respect of a range of difficulties and populations,[13] this is the first large-scale study that aims to assess this intervention with dual diagnosis patients. It is also the

first study to assess the effects of this intervention using a comprehensive assessment battery designed to measure a range of outcomes relating to alcohol use, mood and social and occupational functioning.

However, in line with our previous pilot trial,[14–16] we anticipate to detect a statistically and/or clinically meaningful positive effect for the intervention.

Contributors CF, EK, VA and DM conceived of and wrote the procedures which form the basis of the trial protocol. VA and DH wrote the initial manuscript which was subsequently edited by EM. All authors have read and approved the final manuscript.

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Competing interests None declared.

Ethics approval St. Patrick's University Hospital Research Ethics Committee.

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