Protocol Version and Date:

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Trial Title:

Use of text messaging support to aid smoking cessation in patients presenting for surgery – a single site randomised control trial. TextPOP

Setting:

Westmead Hospital, NSW, Australia 2145

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Funding

An ACI grant has been lodged for $30,000

Background and rationale

Tobacco use is a major global health problem and one of the largest preventable causes of death and disease in Australia [1 2](https://paperpile.com/c/eW6J51/mswh+rQQa).  Over 14% adults aged over 18 years in Australia are daily smokers [2](https://paperpile.com/c/eW6J51/rQQa). The reported rates of smoking amongst the surgical population is varied with up to 20-30% quoted in some studies [3 4](https://paperpile.com/c/eW6J51/xdWk+pi9h). It is well documented that patients who are smokers have higher rates of perioperative complications such as respiratory, cardiac and wound related complications [5](https://paperpile.com/c/eW6J51/kI3r) . This increased morbidity leads to higher mortality rates, increased length of hospital stay and higher health care costs. Improving preoperative smoking cessation rates has been shown to reduce surgical and anaesthetic complications leading to better outcomes for patients [6](https://paperpile.com/c/eW6J51/REXo).

In 2015-16 there were over 2.2 million elective admissions involving surgery in Australian public and private hospitals [7](https://paperpile.com/c/eW6J51/TxY0).  Undergoing an operation creates a unique encounter between the patient and a variety of health care professionals within the health care system including surgeons, anaesthetists, physicians, nurses and allied health staff. Making and maintaining behavioural lifestyle changes can be a challenging adaptation which requires an individual to progress from a state of precontemplation through the stages of contemplation, followed by preparation, action and finally maintenance in order for that change to be sustained [8](https://paperpile.com/c/eW6J51/C5Ki). This encounter with the health care system occurs at a time when patients maybe more receptive to lifestyle changes and provides a “teachable moment” to capture the patient in a period when they may be able to transition from the stage of precontemplation and begin to make positive behavioural changes such as smoking cessation [5 9](https://paperpile.com/c/eW6J51/kI3r+tEzP)

Smoking is associated with an increased risk of complications related to surgery. These risks can be reduced if the patient quits before surgery. Additionally, patients preparing to undergo surgery are more likely to consider and succeed at quitting smoking due to 1) the motivation of reducing surgery associated complications and 2) a period of non-smoking is enforced during the patient’s hospital stay. Therefore, any techniques to further improve the patient's chances of successfully quitting are likely to have a significant impact on the health of many Australians.

Unfortunately, many of the conventional smoking cessation techniques such as counselling and medication are relatively expensive and are not available to all participants. In contrast text messaging support to remind, encourage and motivate patients to quit smoking is economical and has been shown to be effective.

Preoperative interventions such as behavioural support and nicotine replacement therapy can increase short-term smoking cessation and may reduce postoperative morbidity [10](https://paperpile.com/c/eW6J51/UgGE). In contrast to conventional interventions, mobile phone-based interventions are cheap, widely accessible, and scalable to large populations [11](https://paperpile.com/c/eW6J51/6vwq). However, the benefits of mobile phone-based interventions for smoking cessation in the perioperative setting has not been evaluated.

TEXT ME is a simple and cost-effective program utilising mobile phone text messages to remind, encourage, and motivate patients to adopt positive behavioural and lifestyle changes. The program has been shown to reduce cardiovascular disease risk, including decreasing rates of smoking, in patients with coronary heart disease [12 13](https://paperpile.com/c/eW6J51/HQ6c+FAVG). We hypothesise that an implementation of the TEXT ME program targeting smokers scheduled for elective surgery will decrease rates of smoking and postoperative morbidity.

Mobile phones are becoming increasingly utilised in the delivery of health-care information and services with text messaging in particular being utilised for the delivery of a variety of services including medication adherence, appointment reminders and the monitoring and management of chronic diseases [11](https://paperpile.com/c/eW6J51/6vwq).  Smoking cessation services internationally are increasing the use of mobile phone based support with text messaging being an integrated adjunct to routine clinical practice [11](https://paperpile.com/c/eW6J51/6vwq).  The evidence for the use and efficacy of text messaging systems to reduce smoking rates is now well established [14](https://paperpile.com/c/eW6J51/2SQO).

Objectives

Smoking in the perioperative setting leads to increased surgical and anaesthetic complications. It has been demonstrated that by reducing perioperative smoking rates it can lead to a reduction in these complications, resulting in better outcomes for both patients and health care systems. Undergoing an operation creates a unique encounter between the patient and a variety of health-care professionals. It occurs at a time when patients maybe more receptive to lifestyle changes and provides an opportunity for a “teachable moment” when the patient may be willing to adopt and sustain a positive behavioural change. In contrast to conventional smoking cessation interventions (such as behavioural psychotherapy and pharmacotherapy) which tend to be labour intensive, require higher contact hours and likely higher costs, mobile phone based text messaging systems are a simple, widely available and cost effective intervention that have been successful in reducing smoking rates. The use of such text messaging interventions for smoking cessation in the perioperative setting is yet to be fully utilised and evaluated. TEXT ME is a mobile phone based text messaging program used to remind, encourage and motivate patients to adapt positive lifestyle changes. We aim to implement this program targeting current smokers scheduled for elective surgery with the primary objective of decreasing self-reported smoking rates (at 12 weeks) in the perioperative period and subsequently postoperative morbidity.

Trial Design

This project will utilise deliver a m-Health smoking cessation intervention opportunistically targeted to a time point at which patients have been shown to be particularly receptive to behaviour change (before a surgical procedure). Inclusion criteria will be patients booked for surgical procedures in a large metropolitan hospital who have a self-reported history of smoking. Inclusion criteria include access to an active mobile phone and ability to understand written English. Participants will be randomised 1:1 in a single blinded randomised control trial to either usual care or usual care plus a 12 week smoking cessation intervention delivered via 4 SMS messages / week. SMS messages will include 24 smoking cessation messages and 24 general message which include 1) healthy lifestyle (i.e. diet and physical activity) and 2) information specific to Westmead Hospital pre-admission and surgical services (eg. Parking locations, typical clinic duration, items to bring etc.).

The primary outcome of self-reported smoking cessation will be assessed at 12 weeks and 12 months.

Study Setting

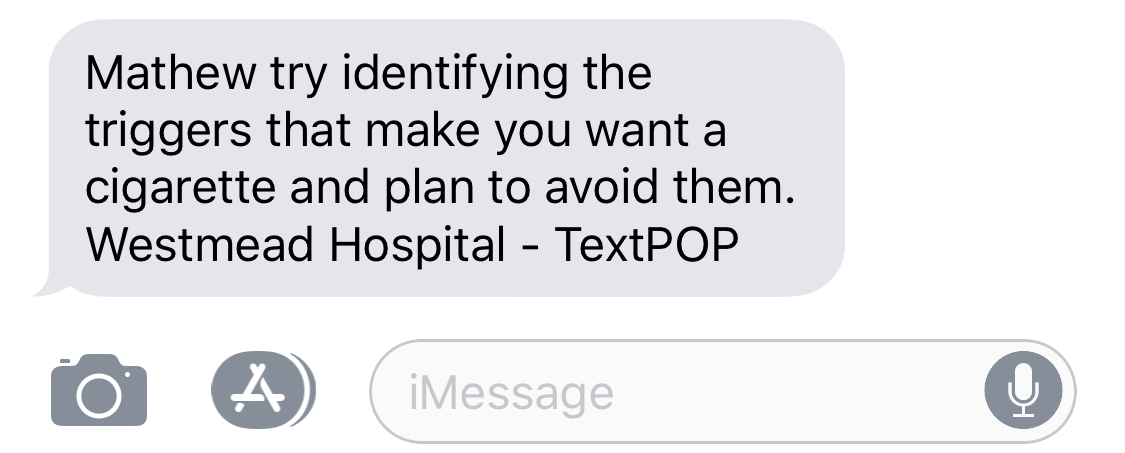
This study will be performed at Westmead Hospital, NSW. It will be carried out in the admissions office and the pre-admissions clinic.

Eligibility Criteria

Inclusion criteria will be patients booked for surgical procedures in a large metropolitan hospital who have a self-reported history of smoking. Inclusion criteria include access to an active mobile phone and ability to understand written English.

Intervention

This project will utilise deliver a m-Health smoking cessation intervention opportunistically targeted to a time point at which patients have been shown to be particularly receptive to behaviour change (before a surgical procedure). Inclusion criteria will be patients booked for surgical procedures in a large metropolitan hospital who have a self-reported history of smoking. Inclusion criteria include access to an active mobile phone and ability to understand written English. Participants will be randomised 1:1 in a single blinded randomised control trial to either usual care, or usual care plus a 12 week smoking cessation intervention delivered via 4 SMS messages per week. SMS messages will include 24 smoking cessation messages and 24 general message which include 1) healthy lifestyle (i.e. diet and physical activity) and 2) information specific to Westmead Hospital pre-admission and surgical services (eg. Parking locations, typical clinic duration, items to bring etc.).

Participants will not be encouraged to reply to the messages but all replies will be monitored. Replies indicating that the participant would like opt-out (eg. ‘Stop’) will be responded to with a follow up phone call to confirm they wish to cease involvement in the study. Once confirmed, they will cease to receive further messages. Any reply messages that require a reply (eg. The patient’s reply text suggests that they are experiencing concerning symptoms or expresses a serious concern) will be reviewed with a senior clinician before a response (either text reply or a phone call).

Example Text Message

Outcomes

The primary outcome of self-reported smoking cessation will be assessed at 12 weeks and 12 months.

This research aims to establish the feasibility and effectiveness of a 12 week SMS delivered smoking cessation program delivered during the pre-operative waiting period before a scheduled surgical procedure.

**Primary outcome:**

1) Smoking cessation assessed at the end of the 12 week program and at 12 months by a self-report questionnaire.

The expected outcome of this project (TextPOP) is that the TEXT ME mobile phone smoking intervention programme will allow health care professionals to seize the opportunity of a teachable encounter with current smokers in the perioperative period and reduce the self-reported rates of smoking in patients scheduled for elective surgeries to be undertaken at Westmead Hospital. The aim of promoting positive behavioural change and reducing smoking rates in the perioperative period will increase the probability of this transpiring to a sustainable behavioural change and ultimately long-term abstinence from tobacco use. This reduction in smoking rates amongst the surgical population will lead to long term improvements in patients’ cardiovascular health. The secondary outcomes of this study will include a reduction in self-reported smoking rates at 12 months. This study has promise to lead to larger more robust studies in the future evaluating the effects of perioperative smoking cessation using a simple, cost effective text messaging intervention and how this reduction impacts on perioperative complication rates and patient morbidity. The proposed funding of these future projects is yet to be determined.

Participant Timeline

After participants are consented for this trial, the text message programme will be delivered over a 12 week timeframe. Participants will then be contacted at the completion of the text message programme to complete the post-intervention questionnaire regarding smoking cessation.

Sample Size

Based on previous studies of interventions for preoperative smoking cessation 10 and the original TEXT ME study 12, we assumed 3-month smoking cessation rates of 20% and 40% in the control and intervention group, respectively. A total sample size of 212 participants (106 participants per group) was estimated to allow a two-tailed comparison at a significance level of 0.05 to detect an absolute risk difference of 20% with 90% power. To allow an attrition rate up to 30%, we planned to recruit a total of 276 participants (138 participants per group).

Recruitment

All patients booked for an elective surgical procedure at Westmead Hospital are required to complete a patient health questionnaire. Patients are contacted over the phone initially as part of usual care when their health questionnaires are reviewed by pre-admissions nursing staff. Eligible patients will be identified and asked during their routine phone call if they would like to be involved in the study. If they indicate they are willing to be involved in the study, members of the Textpop team will then contact them to enrol them in the study.

Allocation and Blinding

Patients booked for surgery with an expected wait list time of greater than 90 days will be allocated to either usual care or the text messaging support. The text messaging support will consist of 4 messages a week for 12 weeks and will include: 1) messages supporting healthy lifestyle changes such as diet and exercise and 2) practical orientation information for patients attending the hospital pre-admission clinic as well as the smoking cessation support messages.

Eligible participants will be randomised 1:1 into either:

1. Usual care consisting of 1) a mail out of information leaflets with details specific to Westmead Hospital pre-admission and surgical services (eg. Parking locations, typical clinic duration, items to bring etc.) and 2) brief verbal smoking cessation and general health advice at the pre-admission clinic appointment
2. Usual care and the m-Health smoking cessation / general healthy lifestyle intervention

Randomisation will be performed via a secure, password protected web portal (RedCap). Clinic and study personnel will be blinded to the treatment group allocation. Participants will be informed of their allocation in an initial text message confirming whether they are in the intervention or control group. All participants will also receive a reminder message before the 12 week smoking cessation assessment to ask them not to reveal their allocation status to study personnel. These are the only 2 messages that the control group participants will receive. The initial message also details how to opt out of the messages (‘reply ‘stop’ to opt out of these messages’). Participants allocated to the intervention group will also receive the intervention SMS messages as detailed below.

Data Collection and Management

Initial data will be collected from patient health questionnaires and from participants over the phone once consented. The follow up data will be collected in person at the pre-admissions clinic. Data will be collected associate investigators and a research assistant and recorded on a custom electronic data sheet. It will be stored on a password-protected computer in a locked research room.

Statistical Methods

Statistical analysis will be conducted on the principle of intention to treat. Participants will be analysed by the original allocated groups. Statistical analysis will be conducted using SAS® software (version 9.4, SAS Institute Inc., Cary, NC, USA). Continuous variables will be reported as mean (standard deviation) or median (interquartile range), and compared using the t test or Mann-Whitney-Wilcoxon test. Categorical variables were reported as frequency (percentage), and compared using the chi-squared test or Fisher’s exact test. All statistical tests will be 2-tailed with a significance level of 5%. No adjustments for multiple comparisons will be made as the number of pre-defined outcomes is small. Subgroup analysis will be performed by clinical priority category.

Harms

The intervention proposed in this study poses little risk to the participants. The text messages will be supportive in nature, providing the participants with encouragement to quit smoking and engage in positive lifestyle changes in the lead up to their surgery. The message content is validated and extensively reviewed to ensure participants feel supported and motivated. Additionally, the messages will include practical information such as, parking, expected duration of the clinic visit, items to bring etc.

As was the case with the TextMe study (that this study is modelled off), we anticipate benefit for participants of this study, with positive outcomes of decreased rates of smoking and improved peri-operative morbidity. TextMe has been shown to improve cardiovascular disease risk, including rates of smoking in patients with heart disease.

Despite their voluntary involvement in the study, there is a possibility that patients will feel bothered by the regular text messages. However the frequency is relatively low, with four messages per week, during working hours Monday to Friday, for twelve weeks. Additionally, participants will be given clear opt-out instructions if they no longer wish to receive these text messages.

Research Ethics Approval

An HREA application has been lodged with the Western Sydney Local Health District Research Ethics Committee. It is currently pending review.

Consent

Patients will be contacted by phone by a research assistant specifically employed for recruitment and consent. Consent over the phone is necessary for this study as there will be no face-to-face contact with the patients at hospital until much closer to their surgery date.

An abridged version of the recruitment information will be read to the potential participant over the phone, and filled out by the research assistant in discussion with the patient. The full PICF paperwork will then be mailed to the participant for their records. Should they require time to consider their participation, one week will be allowed before making contact once again to gain consent. Should the participant want to opt out of the intervention at any point, there will be clear and simple instructions to do so, by replying 'stop' to any of the text messages.

Confidentiality

Participants will be allocated a study code for the purposes of de-identification. This code will be composed of the investigator's initials, the last 4 numbers of the patient's MRN and the month in which they were consented.

Declaration of Interests

There are no personal or financial interests to declare for this project.

Dissemination Policy

We aim to submit the results of this study for publication, which will be available for fellow healthcare workers and community members to access.

**REFERENCES**

1. [Australian Institute of Health and Welfare. Australia’s health 2016. Australian Institute of Health and Welfare; 2016 Report No.: Australia’s health series no. 15. Cat. no. AUS 199.](http://paperpile.com/b/eW6J51/mswh)

2. [Australian Bureau of Statistics. National Health Survey: First Results, Australia 2014-15. Australian Bureau of Statistics; 2015](http://paperpile.com/b/eW6J51/rQQa)

3. [Schmid M, Sood A, Campbell L, et al. Impact of smoking on perioperative outcomes after major surgery. *Am J Surg* 2015; **210**: 221–9.e6](http://paperpile.com/b/eW6J51/xdWk)

4. [Kamath AS, Vaughan Sarrazin M, Vander Weg MW, Cai X, Cullen J, Katz DA. Hospital costs associated with smoking in veterans undergoing general surgery. *J Am Coll Surg* 2012; **214**: 901–8.e1](http://paperpile.com/b/eW6J51/pi9h)

5. [Australian and New Zealand College of Anaesthetists. Guidelines on Smoking as Related to the Perioperative Period. Australian and New Zealand College of Anaesthetists; 2014 Report No.: PS12.](http://paperpile.com/b/eW6J51/kI3r)

6. [Webb AR, Robertson N, Sparrow M. Smokers know little of their increased surgical risks and may quit on surgical advice. *ANZ J Surg* 2013; **83**: 753–7](http://paperpile.com/b/eW6J51/REXo)

7. [Australian Institute of Health and Welfare. Admitted patient care 2015–16: Australian hospital statistics. Australian Institute of Health and Welfare; 2017 Report No.: Health services series no.75. Cat. no. HSE 185.](http://paperpile.com/b/eW6J51/TxY0)

8. [Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. *Am J Health Promot* 1997; **12**: 38–48](http://paperpile.com/b/eW6J51/C5Ki)

9. [Shi Y, Warner DO. Surgery as a Teachable Moment for Smoking Cessation. *Anesthesiology* 2010; **112**: 102–7](http://paperpile.com/b/eW6J51/tEzP)

10. [Thomsen T, Villebro N, Møller AM. Interventions for preoperative smoking cessation. *Cochrane Database Syst Rev* [Internet] 2014; Available from:](http://paperpile.com/b/eW6J51/UgGE) <http://dx.doi.org/10.1002/14651858.cd002294.pub4>

11. [Whittaker R, McRobbie H, Bullen C, Rodgers A, Gu Y. Mobile phone-based interventions for smoking cessation. *Cochrane Database Syst Rev* [Internet] 2016; Available from:](http://paperpile.com/b/eW6J51/6vwq) <http://dx.doi.org/10.1002/14651858.cd006611.pub4>

12. [Chow CK, Redfern J, Hillis GS, et al. Effect of Lifestyle-Focused Text Messaging on Risk Factor Modification in Patients With Coronary Heart Disease: A Randomized Clinical Trial. *JAMA* 2015; **314**: 1255–63](http://paperpile.com/b/eW6J51/HQ6c)

13. [Burn E, Nghiem S, Jan S, et al. Cost-effectiveness of a text message programme for the prevention of recurrent cardiovascular events. *Heart* 2017; **103**: 893–4](http://paperpile.com/b/eW6J51/FAVG)

14. [Scott-Sheldon LAJ, Lantini R, Jennings EG, et al. Text Messaging-Based Interventions for Smoking Cessation: A Systematic Review and Meta-Analysis. *JMIR Mhealth Uhealth* 2016; **4**: e49](http://paperpile.com/b/eW6J51/2SQO)