PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (see an example) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Design and rationale of the tobacco, exercise and diet messages (TEXT ME) trial of a text message based intervention for ongoing prevention of cardiovascular disease in people with coronary disease: a randomised controlled trial protocol.
AUTHORS	Chow CK, Redfern J, Thiagalingam A, Jan S, Whittaker R, Hackett M, Graves N, Mooney J, Hillis GS

VERSION 1 - REVIEW

REVIEWER	Tom Briffa Research Associate Professor and Head Cardiovascular Research Group The University fo Western Australia Adjunct Professorial Fellow The George Institute I have and am currently collaborating with authors Redfern and Chow on projects unrelated to this manuscript.
REVIEW RETURNED	27/11/2011

THE STUDY	Are any participants likely to receive another type of secondary prevention program e.g. hospital cardiac rehabilitation following their admission to hospital with coronary artery disease? If yes, how will the investigators control for this? What is the timeline for recruitment into the study following admission to hospital with either acute coronary syndrome or a diagnosis of diagnosis of coronary artery disease. Are the latter group required to be symptomatic and is their motivation for lifestyle change likely to be equal to survivors of an acute attack? Are the investigators actively discouraging replies from recipients of TEXT ME messages? If yes, how will efforts by those in the intervention group to contact the investigators and other healthcare providers (eg, general practitioner) be controlled and presumably monitored? What is the process for contacting participants if the TEXT ME messages fail to be delivered (e.g. full mail box)? Is there evidence to support the decade old baseline value of the primary outcome LDL cholesterol used to power the study is applicable now given the increase use and strength of statins with time? Unable to find and therefore comment on Figure 1.
REPORTING & ETHICS	Remove replication of ethics approval.
GENERAL COMMENTS	A well written trial protocol with comprehensive methods to match applying text messaging to the prevention of cardiovascular disease.

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REVIEWER	A/Professor Robyn A Clark RN, RM, ICU Cert, BN, MEd, PhD, (Life Member ACCCN) FRCNA. NHMRC Research Fellow, School of Nursing and Midwifery. Member - Institute of Health and Biomedical Innovation (IBHI). Adjunct Sansom Institute, UniSA. Room 342, Level 3 N Block, Ring Rd, Kelvin Grove Campus, Queensland University of Technology Kelvin Grove, QLD, 4059, Australia
REVIEW RETURNED	06/12/2011

THE STUDY	Does the study provide any two-way interaction-describe. Question as to whether this is mixed method design with both quantitative and qualitative methods. Thematic saturation needs to be referenced. Clearly indicate which the statistical tests will be used for each outcome (opposed to overview). Justify the use of a telephone study outcomes to be used for a power calculation of a TEXT study.
RESULTS & CONCLUSIONS	Research Protocol N/A
REPORTING & ETHICS	Need more details of the patient personal data is secured in the SMS software.

VERSION 1 – AUTHOR RESPONSE

Responses to Reviewer: Tom Briffa

• Are any participants likely to receive another type of secondary prevention program e.g. hospital cardiac rehabilitation following their admission to hospital with coronary artery disease? If yes, how will the investigators control for this?

Data will be collected on the use of secondary prevention programs (page 15, paragraph 1, lines 5-7). Yes, it is likely that some participants will receive another type of secondary prevention program. We have not excluded these patients as it is uncertain who will and will not attend secondary prevention programs at the time of recruitment. Based on Australian data, we do not expect more than 20% of those recruited will participate in 1 session of the hospital cardiac rehabilitation program (let alone complete it) (Briffa T et al 2009 MJA). Due to the randomised nature of the study we expect this to be a similar proportion in the intervention and control groups. Our main study outcomes will be reported unadjusted, that is we will not 'control' per se for covariates. However, we will conduct sensitivity analyses and sub-analyses to explore if the intervention effects vary in those receiving or not receiving another type of secondary prevention program.

• What is the timeline for recruitment into the study following admission to hospital with either acute coronary syndrome or a diagnosis of diagnosis of coronary artery disease. Are the latter group required to be symptomatic and is their motivation for lifestyle change likely to be equal to survivors of an acute attack?

For patients admitted to hospital, we have not stipulated a clear timeline for recruitment following admission, rather patients are enrolled when there is a clear timeline around their discharge from hospital. Our study population comprises of patients with ACS (recruited during their index admission) and patients with angiographically confirmed CHD (identified during inpatient admission or though outpatient clinics). It is possible that patients that have an acute coronary syndrome may be more

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motivated than patients who have chronic symptoms or are relatively asymptomatic with their coronary disease. We are collecting information on the acuity of symptoms and whether patients are 'acute' which will enable us to do sub-group analyse in these groups.

• Are the investigators actively discouraging replies from recipients of TEXT ME messages? If yes, how will efforts by those in the intervention group to contact the investigators and other healthcare providers (eg, general practitioner) be controlled and presumably monitored? What is the process for contacting participants if the TEXT ME messages fail to be delivered (e.g. full mail box)?
As highlighted by the reviewer this trial provides a unidirectional intervention whereby participants receive text messages as reminders only. There is no opportunity for participants to discuss ongoing management plans with the research staff. Given this question was also raised by reviewer 2 we have now explicitly stated this aspect of the intervention in the revised manuscript (page 9, paragraph 3, line 4-5).

Participants will be provided with a contact point for any general concerns they may have during the course of the study. This will not include the provision of medical advice and the researcher available for contact will not be involved in any individual analysis. We have included a statement to this effect in the revised manuscript (page 9, paragraph 3, line 5-6).

In terms of contact with other health professionals this will be collected at follow-up and as part of the qualitative component of the study. It is anticipated that randomisation should account for much of this variability between groups if there is any. This is included in the revised manuscript (page 15, paragraph 1, line 7).

A researcher will manage a mobile telephone that will receive any messages received from the participant's phones. This researcher will not participate in any individual level of analysis and will keep a record of all messages received from participants throughout the course of the study. Participants will have the opportunity to withdraw via a text message and the researcher will contact the software manager in order to activate the withdrawal. If the TEXTME mobile phone receives a messages indicating that a participants mailbox is full the researcher will contact the participant to discuss but will not provide any medical advice. This information has now been inserted into the revised manuscript (page 10, paragraph 1, lines 6-13).

• Is there evidence to support the decade old baseline value of the primary outcome LDL cholesterol used to power the study is applicable now given the increase use and strength of statins with time?
We have chosen LDL as primary outcome because high levels have a significant impact on future event rate and Australian published data (COACH) provide the levels (mean LDL 2.94mmol/L SD 0.96) used to calculate power. We agree with the reviewer that the study is now quite old and that more potent statin therapy is now more frequently used. More recent published (n=5,293) Australian data (Heeley EL et al 2010 MJA) state that mean LDL of the population was 2.85mmol/L (SD 0.92) which is very similar to that of the COACH study. However, using data from the COACH study is more appropriate for TEXTME because the sample population and methodology is more appropriate. While, a primary endpoint of mortality or cardiovascular events would be ideal the number of participants required is not possible in this context. While we agree there are problems with all potential surrogate outcomes, we have selected LDL given its impact on events.

We would also like to identify that the study power is calculated based on the 6 month LDL cholesterol level and not the "baseline value" as the reviewer suggests.

• Unable to find and therefore comment on Figure 1.
Figure 1 is provided and we are happy to receive any further comments as required.

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• Remove replication of ethics approval.
Removed from page 8 as there is a dedicated subheading on page 18.

Responses to Reviewer: A/Professor Robyn A Clark
• Does the study provide any two-way interaction-describe.
As previously explained, this protocol does not describe any 2-way interaction and this has now been explicitly stated in the revised manuscript (page 9, paragraph 3, line 4-5).

• Question as to whether this is mixed method design with both quantitative and qualitative methods.
As well as the clinical trial with clinical endpoints, this study includes a significant process evaluation (detailed on page 14-15) that includes a qualitative survey of all participants allocated to the intervention group as well as in-depth interviews of a sub-sample of participants. For this reason we believe it remains a trial comprising a mixture of quantitative and qualitative methodology.

• Thematic saturation needs to be referenced.
Now referenced as suggested (page 15, paragraph 2, line 7) and inserted into reference list (Reference #31).

• Clearly indicate which the statistical tests will be used for each outcome (opposed to overview).
These have been articulated in terms of follow-up point and specific outcomes (page 17, paragraph 2, lines 2-4)

• Justify the use of a telephone study outcomes to be used for a power calculation of a TEXT study.
There are no trials of text message interventions in patients with cardiovascular disease. The mean LDL level was drawn from the telephone trial as it was directed at a similar study population to that recruitied in this study. The projected change was drawn from this telephone study as it was one that was clinically meaningful – maybe good to add somewhere what perencetage of events may be avoided if this change in LDL was made. And it was thought to be tangigle in a text based intervention study.

• Need more details of the patient personal data is secured in the SMS software.
Data exports will be compliant with privacy legislation, centrally managed by the George Institute and held in strict confidence. There will be no access to these data by any third party, including the software developers. This important information about personal data security is now included on page 12 (paragraph 2, lines 8-11) of the revised manuscript.

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