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Behaviour change interventions to improve medication adherence in patients with cardiac disease: Protocol for a mixed methods study including a pilot randomised controlled trial

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ABSTRACT

Background: Suboptimal adherence to medication increases mortality and morbidity; individually tailored supportive interventions can improve patients' adherence to their medication regimens.

Aims: The study aims to use a pilot randomised controlled trial (RCT) to test the hypothesis that a theory-based, nurse-led, multi-faceted intervention comprising motivational interviewing techniques and text message reminders in addition to standard care will better promote medication adherence in cardiac patients compared to standard care alone. The pilot study will assess self-reported adherence or non-adherence to cardiovascular medication in patients referred to a cardiac rehabilitation program following hospital admission for an acute cardiac event and test the feasibility of the intervention. The study will examine the role of individual, behavioural and environmental factors in predicting medication non-adherence in patients with CVD.

Methods: This is a mixed- methods study including a nested pilot RCT. Twenty-eight cardiac patients will be recruited; an estimated sample of nine patients in each group will be required for the pilot RCT with 80% power to detect a moderate effect size at 5% significance, and assuming 50% loss to follow-up over the six month intervention. Participants will complete a paper-based survey (Phase one), followed by a brief semi-structured interview (Phase two) to identify their level of adherence to medication and determine factors predictive of non-adherence. Participants identified as 'non-adherent' will be eligible for the pilot randomised trial, where they will be randomly allocated to receive either the motivational interview plus text message reminders and standard care, or standard care alone.

Discussion: Nurse-led multi-faceted interventions have the potential to enhance adherence to cardiac medications. The results of this study may have relevance for cardiac patients in other settings, and for long-term medication users with other chronic diseases.

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1. Introduction

World-wide, the prevalence of cardiovascular disease (CVD) is increasing rapidly because of changes in population lifestyles (Hauptman, 2008), resulting in major concerns for community health (Zhu, Wang, Zhu, Zhou, & Wang, 2015). Cardiovascular disease has emerged as a leading cause of death and disability

in Australia (Nichols, Peterson, Alston, & Allender, 2014), affecting one in six people and responsible for 16% of the nations' total disease burden. It is the main reason for rehospitalisation (Australian Institute of Health and Welfare, 2014); costs in 2004-5 of AU\$5.94 billion accounted for 11% of Australia's total health expenditure (Australian Institute of Health and Welfare, 2010). Quality of life has been shown to improve for patients with CVD referred to a comprehensive cardiac rehabilitation and secondary prevention program (Shepherd & While, 2012). These programs comprise recovery and preventative activities aimed at modifying cardiac risk factors and enhancing physico-psycho-social function to reduce the risk of subsequent cardiac events (Woodruffe et al., 2014). Cardiac rehabilitation enables changes in patient lifestyles

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Summary of Relevance**Problem**

Cardiovascular disease remains one of the leading causes of morbidity and mortality in Australia and worldwide.

What is already known

Adherence to cardiovascular medication is suboptimal, increasing the risk of mortality and morbidity.

What this paper adds

This is the first multi-method pilot randomised controlled trial of an intervention comprising motivational interviewing techniques and text reminders delivered by nurses to promote adherence to medication. Outcomes will support the development of a full-scale trial of the intervention in cardiac rehabilitation and other health care areas, and to patients with other chronic conditions who take long-term medications.

by providing education and development of skills to reduce cardiovascular risk factors, and to promote adherence to prescribed medications.

Prescription medications, an important form of secondary prevention for CVD, have been a key factor in the 20% reduction seen in mortality rates within one year of diagnosis of acute myocardial infarction (AMI) (Chase, Bogener, Ruppap, & Conn, 2016); and the 28% reduction within three months of AMI between 2006 and 2007 (Kolandaivelu, Leiden, Gara, & Bhatt, 2014). While cardiac medications have been shown to be effective for symptom management and slowing the progression of CVD, consistent adherence to prescribed medication regimes is required to achieve these effects (Hunt et al., 2009).

The World Health Organisation (WHO) defines adherence as 'the extent to which a person's behaviour (taking medications, following a recommended diet and/or executing lifestyle changes) corresponds with the agreed recommendations of a healthcare provider' (Sabaté, 2003, p. 3). Adherence to medications is a challenge, particularly for patients with cardiac disease who often require multiple medications for prolonged periods (World Health Organisation, 2003). The risk of mortality and morbidity in such patients increases if adherence to prescribed medication is suboptimal (Hope, Wu, Tu, Young, & Murray, 2004); yet reported rates of non-adherence vary from 33% to more than 50% (Li, Kuo, Hwang, & Hsu, 2012; Munger, Van Tassel, & LaFleur, 2007; Shah, Desai, Gajjar, & Shah, 2013), contributing to increased numbers of CVD-related Emergency Department visits, hospitalisation, reduced health and well-being, augmented healthcare costs and risk of death (Mukhtar, Weinman, & Jackson, 2014; Whittle et al., 2016). It is therefore important to identify the factors that influence medication adherence (Munger et al., 2007) and provide tailored interventions to improve patients' medication-taking behaviours (Santo et al., 2016).

2. Background

Medication adherence is linked to better clinical outcomes among patients with heart disease, reducing the risk of hospital readmission and death (Ruppap, Cooper, Mehr, Delgado, & Dunbar-Jacob, 2016). Suboptimal medication adherence is a multidimensional issue. Socio-economic and patient-related factors include low educational levels, inadequate knowledge about disease and medications, beliefs about medications and patients' motivation to manage their illness and improve their overall health (Broekmans, Dobbels, Milisen, Morlion, & Vanderschueren, 2010). Lack of social support and psychological, cognitive or medical vulnerability can also play a part (Kronish & Ye, 2013). Factors shown to predict medication non-adherence include low self-efficacy, attitudes and beliefs about medications, low perceived behavioural

control, and lack of social support (Morrison et al., 2015). Patients with concerns about their medications are more likely to report forgetting to take them or intentionally skipping doses (World Health Organisation, 2003). Older people and people in poor health or with co-morbidities are less likely to successfully self-administer (Krueger et al., 2015). Medication self-efficacy and beliefs about medications may also influence the adoption and maintenance of medication adherence behaviours (Bane, Hughe, & McElnay, 2006), and these factors can be affected by psycho-social factors such as the perceived level of social support and mood (Cha, Erlen, Kim, Sereika, & Caruthers, 2008).

Exploring patients' emotions and beliefs while helping to strengthen their self-efficacy may minimise barriers to behavioural change and motivate them to adhere to their medications (Riegel, Masterson Creber, Hill, Chittams, & Hoke, 2016). It is important to promote behavioural change by exploring what drives an individual patient to make changes or to maintain the status quo. This can be achieved by applying motivational interviewing techniques that have been found to be effective in assessing a patient's readiness to change and subsequently moving toward change at an appropriate time (Dart, 2010). Motivational interviewing has been shown to be effective in increasing medication adherence in cardiac patients (Ogedegbe et al., 2008). Also, text messages have been effective in improving the use of prescribed cardiac medications among 65% of patients at six months (Wald, Bestwick, Raiman, Brendell, & Wald, 2014). Understanding the reasons for poor adherence may suggest approaches to novel interventions.

3. Theoretical framework guiding the study

This study will use Bandura's social cognitive theory to enhance the refinement of self-efficacy (Bandura, 1977) and to examine the effects of individual, behavioural and environmental factors on medication adherence. According to the theory, self-efficacy is the pivotal determinant in influencing a person's particular behaviour, directly affecting one's actions and impacting on other determinants (Bandura, 1977, 2004). Bandura (2004) notes that self-efficacy determines the expected outcomes of people's behaviours. Reciprocal determinism is the basic organising principle of behaviour change proposed by this social cognitive theory, with continuous, functional interaction between the environment, the individual and behaviour (Bandura, 1998) (Fig. 1). It assumes that a change in knowledge of health risk and benefits is essential, but requires additional impacts for change to occur (Munro, Lewin, Swart, & Volmink, 2007). Other determinants of behaviour change include behaviours, outcome expectations, expected benefits, beliefs and goals, and perceived facilitators and barriers. The theory proposes that if people perceive that they have outcome control, appropriate behaviour will follow, with sufficiently high self-confidence to overcome otherwise insurmountable barriers (Armitage & Conner, 2000).

Using a theoretical basis to explain relationships between study variables is important when designing effective behavioural change studies (Short et al., 2013). Appropriately designed interventions that employ multiple strategies, such as motivational interviewing to encourage behaviour changes and text messaging strategies to reinforce behaviours, are likely to achieve significant increases in medication adherence in cardiac patients (Al-Ganmi, Perry, Gholzadeh, & Alotaibi, 2016).

4. Methods

4.1. Aim and hypothesis

The study aims to use a pilot randomised controlled trial (RCT) to test the hypothesis that a theory based, nurse-led, multi-faceted

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