**Research Protocol**

**Summary**

Illness perceptions have been found to predict functional outcomes across many illness populations. A new method of measuring illness perceptions, patients’ drawings of their illness, has been validated as an alternative means of assessment. One patient group for whom illness perception drawings have been found to relate to outcomes such as depression and poor illness behaviours are heart patients. Heart patients have also been found to have inaccurate cardiac risk perceptions (Broadbent et al., 2006) and often their mental imagery of what is wrong with their heart is inaccurate (Broadbent et al., 2004). The proposed study will therefore investigate whether a brief, psychoeducational intervention to correct patient’s mental imagery of damage to the heart and how their medication works, can facilitate their recovery through outcomes including return to normal activity, adherence and psychological wellbeing.

70 patients will be recruited from Auckland City Hospital Coronary Care Unity. Participants who are over 18 years of age, can speak English, and have been admitted for an ACS will be included within the sample. Participants will complete questionnaires at baseline, post-intervention and 7 weeks following their discharge from hospital, which will measure their illness beliefs, emotions, health behaviours and will also ask them to draw pictures of how their perceive there heart, both before and after their acute coronary event. After the first assessment, half of the participants will be randomized into the intervention condition, where in addition to standard hospital care, they will also receive the intervention. This study hyothesises that the intervention will improve patients’ illness perceptions as represented through their drawings, and in turn improve their recovery as revealed in functional outcomes such as decreased return to work times and improved adherence. The possible impact of this study clinically, is that if the intervention is proven effective, it could be administered to cardiac patients to help improve their recovery and wellbeing.

**General Information**

* *Project Title*: Improving patients’ understanding of their heart condition through the use of their drawings.
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**Rationale & Background Information**

Illness perceptions, the cognitive representations of illness that individuals use to make sense of their health, have been found to predict behavioural and functional outcomes for individuals across a variety of medical conditions including asthma, rheumatoid arthritis, and mental illness (Broadbent, Kydd, Sanders, & Vanderpyl, 2008; Horne & Weinman, 2002; Scharloo et al., 1998). Although illness perceptions have been most commonly measured through scales such as the Illness Perception Questionnaire (IPQ; Weinman, Petrie, Moss-Morris & Horne, 1996), patients’ drawings have also become validated as an alternative method of measurement. The way that patients draw their affected organs have been found to correlate to outcomes including organ specific anxiety, return to work times and illness behaviours (Broadbent, Gamble, & Petrie, 2006).

One patient group where relationships have been found between illness perceptions measured through drawings and outcomes including depression, poor illness behaviours and longer return to work times are heart patients. Myocardial Infarction (MI) patients have been found to have inaccurate cardiac risk perceptions (Broadbent et al., 2006) and often their mental imagery of what is wrong with their heart is inaccurate (Broadbent et al., 2004). Some patients are incapacitated by believing their heart is more damaged than it actually is, while others do not adhere to treatment advice because they perceive their treatment to be ineffective.

The relationship between patients’ drawings and functional outcomes suggests that an intervention to correct their mental imagery of what is wrong with their heart and how medication can improve their heart disease may improve recovery and adherence to treatment. Currently two illness perception intervention trials have attempted to improve functional recovery in MI patients (Broadbent et al., 2009; Petrie et al., 2002). These interventions involved three to four 30-minute sessions with a health psychologist. These studies found significant differences in illness perceptions and return to work times between the intervention and control groups. However, the interventions focused on changing perceptions measured by questionnaires through discussion rather than through patient drawings and imagery. Measuring illness perceptions by patients’ drawings and the use of a single 15-minute intervention may offer a more practical intervention to integrate into clinical work.

This study therefore aims to extend previous work by investigating whether a brief, psychoeducational intervention to correct patient’s mental imagery of damage to the heart and how their medication works, can facilitate their recovery through outcomes including return to normal activity, adherence and psychological wellbeing.

**Study Goals**

The goal of this project is to investigate whether or not a psychoeducational visual intervention can improve the illness perceptions and psychological and physical wellbeing of Acute Coronary Syndrome patients as represented by patients’ drawings of the heart.

**Study Design**

The proposed study is a randomized controlled trial to investigate whether or not a brief, visual, psychoeducational intervention can correct Acute Coronary Syndrome (ACS) patients’ understanding of what has happened to their heart and how medication works and improve their recovery and wellbeing at a 7 week follow up.

The study will take place over a year as part of the student investigator’s Master’s thesis. 70 ACS patients will be recruited from the Coronary Care Unit at Auckland City Hospital for involvement within our study. Inclusion criteria for participants will be that they have ACS, that they are over 18 years of age and fluent in English. The student researcher will liaise with the nurses on the ward as they will approach the participants first. The student researcher will then approach patients and invite them to take part within the study. Participants of the study will complete assessment at three time points; baseline, post-intervention and follow-up assessment. At baseline, participants will be asked to complete a battery of questionnaires assessing illness perceptions, beliefs about medication, emotional functioning, cardiac anxiety and health behaviours, as well as completing their first set of drawings. Participants will be asked to draw a picture of what they believed their heart looked like both before and after they had their ACS.

After this initial assessment, participants will be randomized into either the intervention or control condition. Individuals in the control condition will receive standard hospitalized care. Participants in the intervention condition will receive standard hospitalized care plus a 15 minute psychoeducational intervention which will be standardized dependent upon their amount of damage as measured by their troponin-t levels and other clinical markers. The intervention will use visual images to demonstrate to the patient the extent of the damage as best estimated by their troponin-t peak level, as well as visual images demonstrating how medications such as aspirin and statin work to keep their heart healthy.

From 24 hours to a week after discharge, all participants will complete a post-intervention assessment that includes the same battery of questionnaires, except for the health behaviours measurement, and a second set of heart drawings.

Finally, participants will be asked to complete follow-up assessment at 7 weeks following their discharge from hospital. At this assessment, participants will be posted out the same questionnaire from the baseline assessment, including the drawings and they will also complete scales assessing their return to normal activity, adherence and some questions about their beliefs about their medication. Participants will also be sent out a request for them to complete blood tests at 7-week follow up. Measuring lipids at this time point is good clinical practice following acute coronary syndrome. This will indicate whether patient’s lipid levels are reducing and whether treatment is working.

**Methodology**

*Intervention*

This study is an intervention study as half the participants will be randomized to receive a brief, visual, psychoeducational intervention. The intervention will be personalized into one of three levels, dependent on the severity of their heart attack based on their troponin-t levels and other clinical makers. Participants will be shown images of the approximate extent of damage their heart has incurred based on these levels (mild, moderate, or severe). They will also be shown visual representations of how their medication works to stabilize the walls of their arteries and to thin their blood to prevent further clots

*Measures*

*Questionnaires.* See Appendices 1,2, & 3 for the questionnaires included in each assessment.

*Patients’ medical notes.* Patients’ medical notes will also be used to gather information about the patient’s ACS. This will include recording biomarker levels, type of ACS, patient history with MI, and risk factors. These notes will also be consulted at follow-up to see patient’s lipid levels from their latest blood test result.

**Safety Considerations**

It is not anticipated that this study will affect the safety of any of the participants within our study, however it is possible that our study may give rise to the incidental finding of depression. As all participants will complete the Patient Health Questionnaire (PHQ-9), which assess depression, some participants may score in a range that typically indicates depression. If this occurs however, those participants will be sent a depression information letter, informing them of this and providing them with the information of health services, should they wish to seek further assistance.

**Duration of the project**

* Ethics approvals January and February 2014
* 1st April- 31st August: Recruitment on the wards, taking participants through the study.
  + Initial invitation to participate & first questionnaire
  + Approximately 24hrs later: Intervention
  + Post-Intervention – before discharge: Second questionnaire
  + 7 weeks post-discharge: Third questionnaire mailed out to participants
* Mid-April through mid-September: follow-ups (7 weeks post-discharge).
* October- December: Statistical analysis and Thesis completion.
* Jan/Feb 2015 results dissemination

**Ethics**

Confidentiality will be maintained through the use of the 3-digit identity code for each participant’s documents. Data will be stored away either in secure electronic files or in locked cabinets. Only the student and her supervisor Elizabeth Broadbent will be able to access the physical and electronic files. Informed consent will be gained from all participants as per the consent form and all participants will have the right to withdraw at any time within the study, as stated within the participant information sheet.

Participants will also be given an information sheet with the researcher’s contact details should they have further questions.

A summary of the study findings will also be available to participants should they choose to request it at the end of the study (31/12/2014).

**Budget**

The costs of this study (printing, postage and intervention development) will all be covered by the University of Auckland. The research student will conduct the research procedures.

Costs of questionnaires and postage are estimated to be approximately $300.

In addition, 2 x $100 Westfield vouchers will be offered as a prize to participants, funded by the University of Auckland.

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