Commentary Article Open Access

Metacognitive Therapy for anxiety and depression in cardiac rehabilitation: Commentary on the UK National Institute of Health Research funded PATHWAY programme

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Article Info

Article Notes
Received: May 08, 2018
Accepted: May 28, 2018

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Keywords
Cardiac rehabilitation
Anxiety
Depression
Metacognitive therapy
Psychological distress
Psychotherapy

ABSTRACT

Anxiety and depression are common amongst cardiac patients undergoing cardiac rehabilitation and are associated with poorer health, poor quality of life and higher economic costs. There is a paucity of effective psychological treatments and their provision in this care pathway. A new treatment that is proving highly effective in mental health settings, named metacognitive therapy (MCT), could offer a way forward. This commentary delineates the problem of psychological distress (defined by anxiety and depression symptoms) in cardiac rehabilitation, highlights the limitations of current treatment and describes the PATHWAY research programme funded by the UK National Institute of Health Research (NIHR) to translate and test the metacognitive therapy in this population.

The importance of psychological distress in cardiac patients

Nearly 100,000 patients attend cardiac rehabilitation (CR) services per year in the UK across 324 CR programmes at an annual total cost of approximately £42 million1-3. Data from the UK National Audit of CR (2017)4 reported that 28% of patients attending CR services experience clinical levels of anxiety and 19% report clinical levels of depression (defined by the Hospital Anxiety and Depression Scale; HADS), highlighting psychological distress is prevalent in this population5-9. The rate of major depression identified using structured interviews (across 8 studies) among patients with myocardial infarction was approximately 20%10-11. However, when moderate to significant depressive symptoms were explored (based on self-report measures; across 14 studies) the rate was approximately 40%10-11.

Anxiety and depression in cardiac patients are associated with a range of negative outcomes, such as lower rates of adherence to treatment, a higher prevalence of high-risk behaviors (e.g., smoking), increased risk of death and further cardiac events7,12-16. Two recent studies conducted in heart disease patients found that anxiety and depression predicted future symptoms of psychological distress, higher rates of hospital readmissions, greater costs to the health-care system, lower quality of life, and poorer prognosis17-18. Unfortunately, there is low effectiveness in managing anxiety and depression in this population which has an impact on the success of CR19. Given the nature of this problem and its impact on the
individual, on health services and society, it is imperative that anxiety and depression can be effectively treated in CR services.

**CR programmes and psychosocial health**

In 2010, the Department of Health implemented a CR commissioning pack. The key aim of the CR programme is to improve physical health and quality of life, and to support people to develop self-management skills. Core components of the patient care plan include health behavior change and education, medical and lifestyle risk factor management (e.g., physical activity, diet, smoking cessation), and psychosocial health. The psychosocial health component is aimed at identifying individuals with clinical levels of anxiety and/or depression, and those with severe and enduring mental health disorders. The second edition of the British Association for Cardiovascular Prevention and Rehabilitation (BACPR) Standards and Core components (2012) suggests referring these patients to psychological practitioners. However, the latest edition (2017) recommends that when clinical levels of psychological distress are related to the cardiac event, and a trained psychologist practitioner exists in the CR team, the patient could be managed within the service. In the absence of a psychologist in the team, individuals should be referred to trained psychological practitioners and their GP should be informed. It is important to highlight that the majority of CR teams in the UK do not include a psychologist.

Although psychological assessment and support are advocated in the CR commissioning pack and in other key UK National Health Service policies, only 19% of CR programmes delivered in group format include a psychological component; 2% of patients receive individual psychotherapy, and no manualized psychological interventions for depression and/or anxiety are available for general use.

Approximately 47% of cardiac patients experience clinical levels of anxiety or depression at the start of CR but only 12% move into the normal range after completing the CR programme (6% for anxiety and 6% for depression); thus, most patients continue to experience psychological distress. Furthermore, there is evidence that over time improvements in psychological distress are not maintained. Attempts to treat psychological distress in cardiac patients include a range of different interventions, i.e., counselling, psycho-education, relaxation, stress management, social support, cognitive behavioural therapy (CBT), and motivational interviewing. Psychological interventions have shown non-significant improvements in reducing anxiety and depression or only small effect sizes. In addition, pharmacological and psychological treatments in cardiac patients have shown limited effects on health-related quality of life and no improvement in cardiovascular outcomes. We propose that the reason for such approaches having limited effectiveness among cardiac rehabilitation patients could be due to the fact that they focus on changing behaviours or challenging the evidence of negative thoughts (which may be accurate in patients with a physical condition) but they do not directly target the regulation of worry and rumination which play a key role in the maintenance of psychological distress.

Given the limitations of existing treatments in this context, there is a need to develop new and effective psychological treatments that can be implemented in the CR care pathway. The identification of this need has led to a recent research programme, named PATHWAY, funded by the UK NIHR to examine the effects of a psychological treatment called Metacognitive Therapy (MCT). MCT has been found effective in pilot work across a range of medical conditions including cancer, Parkinson disease and chronic fatigue syndrome. In addition, a recent systematic review demonstrated that unhelpful
styles of thinking (worry and/or rumination) predicted depression, anxiety, and psychological distress in people with a range of long-term health conditions including heart disease\textsuperscript{41}. Because the control of worry and rumination is specifically tackled in MCT\textsuperscript{42} this approach could prove to be more helpful.

A brief overview of PATHWAY Work-Streams

The PATHWAY programme is a 5-year project funded under the UK NIHR Programme Grants for Applied Research award (RP-PG-1211-20011). It is comprised of three work-streams (WS): WS1 (n=52) is a single-blind randomized pilot study comparing Group-MCT plus usual CR (intervention arm) versus usual CR alone (control arm), with 4 and 12 months follow up. WS2 extends data from WS1 with additional recruitment to give an overall sample of 332 and is a full-scale single-blind randomized controlled trial (RCT). WS3 is a feasibility trial (n=108) comparing Home-MCT plus usual CR (intervention arm) versus usual CR (control arm), with 4 and 12 months follow up.

Seven NHS sites located in the North-West of England are involved in the PATHWAY Programme. Sites participating in WS1 include University Hospital of South Manchester NHS Foundation Trust; Central Manchester University Hospitals NHS Foundation Trust and East Cheshire NHS Trust. Sites added to participate in WS2 include Stockport NHS Foundation Trust and Pennine Acute Hospitals NHS Trust. Sites participating in WS3 include Aintree Liverpool University Hospitals NHS Foundation Trust and Bolton NHS Foundation Trust.

Participants for all work-streams are eligible if they are referred to CR services and they report moderate to high levels of psychological distress (defined by a score of 8 or more on the anxiety and/or the depression subscales of the HADS\textsuperscript{42}) following a recent cardiac event. The primary outcome in WS1 and WS2 is the HADS at post-treatment (4 months). Secondary outcomes for these two work-streams are 12 month HADS score and a range of other symptoms (e.g., post-traumatic stress) and process measures (e.g., metacognitions). The primary outcome in WS3 is the feasibility of delivering MCT in a home-based format and secondary outcomes include the HADS score and other measures of psychological processes and quality of life at 4 and 12 months follow up. All work-streams incorporate health-economics and qualitative components. Service user involvement is a feature of all aspects of the research programme.

The main trial (WS2) and the home-based intervention (WS3) are registered in clinicaltrials.gov, the identifier is NCT02420431 and NCT03129282 respectively. The full protocol for WS2 has been recently published\textsuperscript{43}. In WS2, CR nurses trained in the delivery of manualized MCT will deliver the treatment in groups of patients in addition to usual CR. The group-MCT intervention consists of six weekly sessions over 1–1.5 hours. In WS3, participants will undertake a self-help intervention guided by a treatment manual which contains 6 modules, and CR nurses will provide limited telephone support to offer support and guidance on completing the manual.

The delivery of MCT in these two formats, i.e. group and self-help, includes well-specified techniques for discovering/developing new strategies to regulate worry and rumination, and modify the metacognitive beliefs that maintain unhelpful patterns of thinking.

Conclusion

Provision of effective psychological management of anxiety and depression in CR lacks on a number of levels. One way forward is to develop effective, evidence-based and manualized treatments that can be integrated in the CR pathway. With these aims and objectives, the UK NIHR has funded a programme of research to evaluate the effects of MCT for anxiety and depression in CR patients. This research programme offers a number of important potential impacts. First, we will have valuable data on the effectiveness of MCT applied in this population; second, we will have two structured and manualized interventions (group and self-help); third, we will have information on the longer-term health and economic impact of treatment; finally, we hope to gain valuable knowledge on the conditions required for the implementation and further development of interventions for effectively treating psychological distress in cardiac patients.

It is hoped that the PATHWAY programme will add evidence on MCT among heart disease patients referred to CR services experiencing psychological distress, which is important to improve clinical outcomes and enhance patient quality of life and cost-effectiveness.

Conflict of interest statement

Professor Adrian Wells is the developer of MCT and a co-director of the MCT Institute. He is chief investigator and grant holder on the PATHWAY programme. He has authored books on cognitive therapy and metacognitive therapy and receives royalties from these. The authors declare no other conflicts of interest.

Funding information

The PATHWAY Programme is funded by the UK National Institute for Health Research (NIHR) under its Programme Grants for Applied Research scheme (RP-PG-121120011).

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