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Evaluating the efficacy of an integrated motivational interviewing and multi-modal exercise intervention for youth with major depression: Healthy Body, Healthy Mind randomised controlled trial protocol

Yasmina Nasstasia[a,*], Amanda L. Baker[b], Sean A. Halpin[a], Leanne Hides[c], Terry J. Lewin[d], Brian J. Kelly[d], Robin Callister[e]

[a] School of Psychology, University of Newcastle, Callaghan, NSW 2308, Australia
[b] School of Medicine and Public Health, Faculty of Health and Medicine, University of Newcastle, Callaghan, NSW 2308, Australia
[c] School of Psychology, University of Queensland, St Lucia, QLD 4072, Australia
[d] Priority Research Centre for Brain and Mental Health Research, School of Medicine and Public Health, Faculty of Health and Medicine, University of Newcastle, Callaghan, NSW 2308, Australia
[e] School of Biomedical Sciences and Pharmacy, Priority Research Centre for Physical Activity and Nutrition, University of Newcastle, Callaghan, NSW 2308, Australia

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ABSTRACT

Background: Recent meta-analytic reviews suggest exercise can reduce depression severity among adults with major depressive disorder (MDD); however, efficacy studies with depressed youth are limited. Few studies have investigated the efficacy of multi-modal exercise interventions in this population, addressed treatment engagement, or explored the differential effects of exercise on depressive symptom profiles.

Objectives: This paper describes the study protocol and recruitment pattern for an assessor blinded, two-arm randomised controlled trial investigating the efficacy of an integrated motivational interviewing (MI) and multi-modal exercise intervention in youth diagnosed with MDD. Associations between depressive symptom profiles (cognitive, somatic and affective) and psychological, physiological (fitness), and biological (blood biomarker) outcomes will also be examined.

Methods: Participants aged 15–25 years with current MDD were recruited. Eligible participants were randomised and stratified according to gender and depression severity to either an immediate or delayed (control) group. The immediate group received a brief MI intervention followed by a 12-week small group exercise intervention (3 times per week for 1 h), all delivered by personal trainers. The delayed control group received the same intervention 12-weeks later. Both groups were reassessed at mid-treatment or mid-control, post-treatment or post-control, and follow-up (12 weeks post-treatment).

Results: 68 participants were recruited and randomly allocated to an intervention group.

Conclusion: This trial will increase our understanding of the efficacy of multi-modal exercise interventions for depression and the specific effects of exercise on depressive symptom profiles. It also offers a novel contribution by addressing treatment engagement in exercise efficacy trials in youth with MDD.

1. Introduction

1.1. Background

Major depressive disorder (MDD) is a heterogeneous disorder characterised by a diverse symptom profile [1,2]. MDD is highly prevalent in youth [3,4] and associated with comorbid eating [5,6], anxiety and substance use disorders, and increased risk of suicide completion [4,7–9]. Established treatment approaches for youth are limited by accessibility to psychological therapies and side-effects of antidepressant medications [10,11]. Exercise has physical and psychological benefits, with antidepressant effects documented among adult populations [12–14]. A small number of studies have reported similar benefits among youth populations [11,15]; however, methodological issues have constrained the generalisability of findings [10,16,17]. Benefits have been established for aerobic exercise programs but not for those combining aerobic exercise and resistance training in a multi-modal approach [18–20]. Exercise studies across the lifespan have also predominately focused on change in global depression severity scores and little is known about the impact of exercise on

* Corresponding author.School of Psychology, Behavioural Sciences Building, University of Newcastle Callaghan, NSW 2308, Australia.
E-mail address: yasmina.nasstasia@newcastle.edu.au (Y. Nasstasia).

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depressive symptom profiles (cognitive, somatic and affective) or the relationship between depressive symptoms and psychological, physiological and biological factors.

Establishing the effectiveness of exercise for MDD is further constrained by high dropout rates particularly among people with more severe depressive symptoms [21]. Interventions that enhance readiness and engagement in exercise programs and address potential barriers may help address motivational constraints [13]. Substantial research supports the effectiveness of Motivational Interviewing (MI) in modifying health behaviour [22]. Recently, MI has also been applied as an effective pre-treatment engagement strategy [23,24], but to the best of our knowledge its benefits as a pre-exercise intervention strategy among youth with MDD are yet to be determined.

We recently conducted a pilot study investigating the feasibility of integrating a pre-exercise MI intervention designed to engage young people with MDD in exercise training and assessed the effects of the intervention on depression symptom profiles [25]. In the current study, the pilot MI intervention was adapted for delivery by personal trainers and integrated with an exercise intervention in the context of a randomised controlled trial.

1.2. Objectives and hypothesis

The primary aim of this study is to evaluate the efficacy of a 12-week integrated MI and multi-modal exercise intervention on depression diagnosis and overall depression severity in youth diagnosed with MDD. Secondary aims are to determine whether there are: 1) differential changes in depressive symptoms (cognitive, somatic and affective); 2) persistence of treatment effects over 24 weeks (from recruitment) and any consequences of delaying treatment; 3) changes in anxiety symptoms; and 4) associations between changes in depression symptoms and program adherence, as well as changes in physical fitness, psychological and blood biomarker measures. It is hypothesised that the exercise program will improve overall depression severity scores in the intervention group relative to the control group, differentially effect depressive symptom subscales, and that these benefits will persist at follow-up.

2. Research design and methods

2.1. Study design

This is an assessor blinded, two-arm, randomised controlled trial (RCT) examining efficacy and differential depressive symptom effects of an integrated MI and multi-modal exercise intervention in youth with MDD. Participants were stratified by gender and overall depression severity and randomised either to the immediate (IM) intervention or control/delayed (CTRL/DL) group. A flow chart illustrating the study design and participant recruitment is presented in Fig. 1. Assessments were conducted at baseline (T1), mid-treatment or mid-control (T2, Wk6), post-treatment or post-control (T3, Wk12) (which doubled as the pre-treatment for DL), mid-treatment for DL (T4, Wk18), follow-up for IM or post-treatment for DL (T5, Wk24), and follow-up for DL (T6, Wk36). Data from the CTRL/DL group served both as a control condition (T1 to T3) and as a basis for evaluating treatment maintenance effects (T3 to T6) when combined with IM group data (T1 to T3, and T5). This research study was prospectively registered with the Australian New Zealand clinical trials registry (ANZCTR: ACTRN12613000638730) and approved by the University of Newcastle, Human Research Ethics Committee (H2012-0114) and the Hunter New England Local Health District Human Research Ethics Committee (15/04/15/4.05). The design, conduct and reporting of this study will comply with the Consolidated Standards of Reporting Trials (CONSORT) guidelines [26,27].

2.2. Participants: eligibility, screening and recruitment

Participants were recruited from the local community and University population and fell within the World Health Organization youth age range of 15–25 years. They had to have current MDD, as assessed by a clinical psychologist utilising the structured clinical interview for DSM-IV Axis 1 disorders (SCID-1 Research Version) [28]. The SCID is widely regarded as the gold standard interview for diagnosis of depression. The eligibility and exclusion criteria for the study are detailed in Table 1. Individuals were excluded if they had medical contraindications to exercise or significant psychiatric co-morbidities such as bipolar or psychotic disorders or eating disorders where exercise was contraindicated. Participants were included whether or not they were receiving other treatment for MDD (counselling, pharmacotherapy), or if they reported engaging in modest levels of physical activity; this was intended to increase the generalisability of findings in this age group within the context of usual clinical practice.

2.2.1. Recruitment

Recruitment occurred across three waves between May 2013 and September 2015. A range of strategies were adopted to target recruitment of individuals with varied levels of depression severity (mild to severe). Strategies included: advertisements on community television, social media, YouTube, newspapers, community radio, University website, flyers on University and community notice boards, emails and letters to clinicians working across a range of local, youth health services, general and psychology practices. All participants were recruited from the Newcastle region of New South Wales, Australia.

2.2.2. Screening

Participants expressing interest in the study were screened using a specifically designed phone screen to determine their initial eligibility. This phone call was used to provide information about the study and collect relevant screening information using a structured interview. Verbal consent was obtained prior to screening. Participants were asked to provide relevant sociodemographic data (e.g., age, gender), pregnancy and current depression status. They were screened for current and past treatment of depression, suicidality, any associated co-morbidities and family history of depression. Participants were also screened for any major medical problems that may interfere with their capacity to engage in exercise. Current physical activity and anthropometric information (estimated weight and height) were also collected.

2.2.3. Psychological screening assessment measures and suicide risk protocol

Participants were screened for current depression using the Beck Depression Inventory-Fast Screen (BDI-FS) [29] administered during the phone screen. The BDI-FS is a seven-item version of the Beck Depression Inventory (BDI-II) designed to assess depressive symptoms in accordance with DSM-IV criteria for a major depressive episode in adolescents (> 13 years) and adults. The BDI-FS provides a valid and reliable measure of cognitive and affective depressive symptoms with item scores ranging from 0 to 3 and a maximum total score of 21 [29]. Participants who reported current suicidal ideation were further assessed to determine intent/plan for suicide using a specifically designed suicide risk assessment protocol. Participants considered to be at imminent risk of suicide were referred to relevant mental health services and/or authorities were contacted and they were excluded from the study. Participants were also screened for anxiety symptoms using the Generalised Anxiety Disorder Scale (GAD-7) [30]. The GAD-7 is a seven-item brief measure linked to DSM-IV criteria for assessing generalised anxiety symptoms, which has demonstrated reliability and validity [31].