Final Report

‘Simple Interventions Trial’

The effectiveness of simple psychological and physical activity interventions for high prevalence mental health problems in young people: a factorial randomised controlled

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Main messages

- Young people who were help-seeking for problems with depression and/or anxiety showed significant improvement in symptoms over the course of a 6 week intervention period.

- Interventions were focused on skill-building and engaging in physical activity and delivered in a factorial randomised controlled trial design.

- Young people who received the physical activity intervention reported the greatest improvement in depression symptoms and this difference was clinically meaningful.

- These significant results are for an innovative intervention that does not require physical activity to take place within session but allows for a psychologist or allied health professional to apply a behavioural approach to encourage an increased engagement in physical activity in a young person’s life.

- Any intervention that can address health risk behaviours in young people with mental health problems is of significance given that only 1 in 4 young people in the general population meet the current guidelines for recommended activity levels.

- In contrast, of the 346 young people seeking help for mental health problems screened for inclusion in the current study, only 6% were currently meeting the guidelines for physical activity.
The interventions were easy to deliver and acceptable to young people as indicated by the high attendance rates at the weekly sessions.

Executive summary

This project aimed to evaluate whether simple psychological and physical activity interventions were effective for treating sub-threshold or mild to moderate depression and anxiety disorders in young people and, if so, which interventions (or their combination) are most effective for various types or severities of clinical presentations. These interventions were compared to the control conditions of supportive counseling and lifestyle psycho-education.

Given the high prevalence and negative consequences associated with even sub-threshold or mild to moderate levels of depression and anxiety disorders in young people, we were interested in exploring whether skill-building and behavioural interventions are effective and feasible to deliver to young people with non-severe mental health problems. In particular, there is emerging evidence to support problem solving therapy and physical activity interventions in reducing symptoms of mental distress in young people, although we identified a need for further research.

Over the course of 6 weekly sessions, young people involved in the current study received a combination of a psychological and a physical activity intervention. Young people were randomised to receive problem solving therapy or supportive counseling in addition to a physical activity intervention or psycho-education on
lifestyle issues. The results showed a clinically meaningful difference in depression symptoms in those who received the physical activity intervention, regardless of the type of psychological intervention they received. The physical activity intervention was delivered within a behavioural activation framework, focusing on developing a tailored plan for each young person and targeting the barriers to exercising using a motivational enhancement approach. These significant results are for an innovative intervention that does not require physical activity to take place within session but allows for a psychologist or allied health professional to apply a behavioural approach to encourage increased engagement in physical activity in a young person’s life. It is also the first study of a physical activity intervention to include young adult males in the 20-25 year age group. The outcomes of this study indicate that it is feasible and effective to deliver a physical activity intervention within a behavioral activation approach to help-seeking young people.
Context

The primary aims of the research study were to evaluate whether simple psychological and physical activity interventions were effective for treating sub-threshold or mild to moderate depression and anxiety disorders in young people and, if so, which interventions (or their combination) are most effective for various types or severities of clinical presentations. These interventions were compared to the control conditions of supportive counseling and lifestyle psycho-education.

Prior research has indicated that the prevalence of mental disorders in young people is the highest of any age group (1), with the onset of high prevalence disorders such as depression, anxiety and substance use peaking within the age range of 18 to 24 years (2). The long-term consequence of impairments to social functioning, poor education and employment achievement and attainment, and increased risk of self-harm and suicide are not solely associated with severe forms of mental disorders. Considerable impairment in functioning is associated with what are often referred to as ‘sub-threshold’ mental health problems, which are equally, if not more, prevalent (3-5).

However, the majority of treatment studies that have contributed to the evidence base for young people with depression and anxiety have included participants with full-threshold level of disorder. It remains unknown whether less complex or intensive interventions, often used as control conditions in treatment studies of more severe disorders, would be feasible and effective treatments for those experiencing milder or sub-threshold forms of mental health problems. Effective
treatments for this population that target early phases or sub-threshold levels of disorder have the potential to reduce the risk of persistence and recurrence (6-8), and impairments in social, educational and vocational functioning (4-6).

The majority of psychological treatment trials for young people with depression and/or anxiety disorders have used cognitive-behaviour therapy (CBT), or adaptations of this therapy, as the intervention (9, 10). Brief forms of this therapy have rarely been offered, with 12 sessions as standard (9) and most trials have been based in specialist mental health settings, making it unclear whether the intervention would be feasible or acceptable for young people with mild to moderate or sub-threshold forms of disorders who present for treatment in primary or enhanced primary care settings.

It has recently been argued that simpler models of CBT that focus on one or two core components, such as behaviour activation and problem solving, may be more beneficial than full CBT for young people (11). Indeed, the most recently published meta-analysis of psychotherapy for depressed children and adolescents demonstrated that both cognitive (i.e., CBT) and ‘non-cognitive’ (for example, behavioural activation, family therapy, behavioural problem solving, group support and social skills training) strategies were equally effective in treating depression (10), suggesting that the specific targeting of cognition might not be a necessary component of effective treatment in young people (12). Further, it has been argued that young people appear to be more interested in treatment that offers them a chance to be listened to and to learn new skills rather than develop a deeper
understanding of the psychological processes that contribute to their behaviour (13). Combined, these findings suggest the importance of exploring alternative psychotherapies to CBT that may be more acceptable and effective in younger populations with mild to moderate or sub-threshold levels of disorder.

An additional overarching criticism of interventions for young people with depression and anxiety symptoms is that health risk behaviours that co-occur with mental health problems tend to be overlooked (12). These health risk behaviours include substance use, eating problems and low levels of regular physical activity. Interventions that can incorporate behavioural activation, such as problem solving therapy (14-16) and physical activity interventions (17), are beginning to be explored as potentially effective interventions in reducing depression and anxiety symptoms in young people.

Problem solving therapy (PST) aims to assist a person in learning to cope more effectively with their current difficulties, as well as developing skills that can be used in other settings and times in their life (18). PST aims to achieve this by systematically generating solutions to current problems and implementing a structured plan to resolve the difficulties, thereby introducing new behaviours and skills to effectively solve everyday problems (19). The therapy focuses on how to implement changes in the ‘here and now’ rather than working through the meaning and impact of past experiences (19, 20). Given the relationship between stressful life events and the early onset of depression (21), PST has face validity as an intervention among young people. To date, its effectiveness has been evaluated in two studies in
this age group, providing a preliminary evidence-base for using PST as an intervention in young people with depressive symptoms (15, 16).

As mentioned above, health risk behaviours, including low levels of physical activity, tend to be overlooked in psychological interventions with young people, although both mental health and physical health benefits have been found (12). Although based on a small number of trials of variable quality, a systematic review of exercise interventions in predominantly healthy children and young people found positive short-term effects on self-esteem, with no reported adverse effects (22). A more recent systematic review of exercise in the prevention and treatment of depression and anxiety in children and young people (17) found a small effect in favour of exercise, however, again, the number of included trials was small and their quality variable. The evidence base for the effectiveness of physical activity interventions in children and young people who are experiencing mental health problems is scarce as the majority of trials have been conducted in healthy populations. The evidence base for the effectiveness of physical activity interventions in young people aged 20-25 years is similarly slight. The research activity includes three small RCTs of poor methodological quality, which, in addition to this limitation, only included female participants. Two of the three trials demonstrated a greater reduction in depression scores for those who participated in group-based aerobics (23) or running programs (24) compared to placebo conditions of stretching or usual activity. The third trial did not demonstrate any group differences in depression outcomes for those randomised to high or low intensity exercise (treadmill running in groups), or a stretching control group, with all three groups improving over the 10 week
intervention period (25). Combined, these studies indicate the potential of physical activity treatment for depression, however the limitations of the studies, including the selection of females only, limit the robustness and generalisability of the results. Further high-quality studies are required to evaluate whether physical activity is an effective treatment for depression and anxiety in young people, particularly those with emerging symptomatology; a major aim of the current study.

In summary, there is emerging evidence to suggest that PST and physical activity interventions may have benefits in reducing symptoms of mental distress, particularly depression, in younger populations, although there is a need for further research that utilises adequate control conditions. It is also of interest to explore the effects of less complex or intense interventions separately and whether there are additional benefits gained from delivering the interventions together. These research questions formed the primary aims of the study reported here, referred to as the ‘Simple Interventions Trial’.

**Implications**

Although there were significant improvements in depression and anxiety symptoms overall in the young people who participated in the Simple Interventions Trial, those who received the physical activity intervention, regardless of the type of psychological intervention received, showed significantly greater improvement in depression scores. The robust effect of the physical activity intervention on depression symptoms was a clinically significant finding. The physical activity intervention was delivered within a behavioural activation framework, focusing on
developing a tailored plan for each young person and targeting the barriers to exercise using a motivational enhancement approach. It is also the first study of a physical activity intervention to include young adult males in the 20-25 year age group. The outcomes of this study suggest that it is feasible and effective to deliver a physical activity intervention within a behavioral activation approach to help-seeking young people.

**Approach**

*Methods and design*

Full details of the methods and design of the study were included in a publication of the study protocol (26). The trial was registered as ACTRN12608000550303 with the Australian New Zealand Clinical Trials Registry (ANZCTR) and was approved by the Melbourne Health Human Research and Ethics Committee.

The Simple Interventions Trial utilised a factorial RCT design to allow for the possibility of considering the effects of both the interventions separately and the effects of delivering the interventions together (27). The trial was based in headspace Sunshine (urban Western region of Melbourne); a youth mental health service that provides assessment and psychological and/or psychiatric treatments to young people aged 12-25 years, in addition to primary health care, vocational and educational assistance and specialist substance use services. These services are delivered in a “one-stop shop”, youth-friendly service environment staffed by general practitioners, psychologists, psychiatrists and other allied health professionals. headspace Sunshine is led by a consortium of partners managed by
Orygen Youth Health Research Centre.

Sample and inclusion criteria

All help-seeking young people aged 15-25 years referred to headspace Sunshine were screened for eligibility, with informed consent obtained from all participants. Inclusion criteria were: depressive/anxious symptoms of more than one week’s duration or a decline in functioning over the past month, and no prior formal treatment (e.g., psychological intervention provided by a registered psychologist or pharmacotherapy of at least 4 weeks’ duration). Exclusion and withdrawal criteria were: psychotic symptoms and/or specific suicidal plan or intent; already exercising according to Australian government guidelines (i.e., daily moderate to vigorous physical activity of 60 minutes duration for under 18 years; four times per week of 30 minutes of moderate to vigorous physical activity for those over 18 years (28, 29); organic mental disorder; intellectual disability.

The interventions were delivered in 6 sessions on a weekly basis by research psychologists and involved a combination of: a) Psychological intervention: problem solving therapy (PST; active condition) or supportive counseling (control condition), AND b) Physical activity intervention: behavioural intervention (active condition) or psycho-education (control condition).

A total of 176 young people were randomised into the study from 346 who were initially screened for inclusion. The baseline demographics are included in Table 1. The demographics of the sample were consistent with young people who are
presenting to headspace centres nationally in terms of mean age and gender distribution.

**Table 1. Baseline demographics of participants.**

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
<th>N</th>
<th>%</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>17.6</td>
<td>2.44</td>
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<tr>
<td>Female</td>
<td></td>
<td></td>
<td>106</td>
<td>61</td>
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<tr>
<td>Age impact on functioning</td>
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<td>3.05</td>
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<tr>
<td>Duration of symptoms (months)</td>
<td>14.03</td>
<td>18.03</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family history (present)</td>
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<td></td>
<td>106</td>
<td>61</td>
</tr>
<tr>
<td>Living with parents/siblings/relatives</td>
<td>139</td>
<td>80</td>
<td></td>
<td></td>
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<tr>
<td>In a relationship</td>
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<td></td>
<td>48</td>
<td>28</td>
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*Interventions*

A comprehensive treatment manual for each intervention was prepared. The PST intervention progressively worked through the seven steps of PST, namely: 1. Identifying the young person’s problem/s; 2. Selecting one or two key problems; 3. Identifying goals; 4. Generating solutions; 5. Choosing a solution; 6. Creating a SMART (specific, measurable, achievable, relevant, time-limited) plan; and 7. Reviewing progress/evaluating the plan (19). The supportive counselling intervention was based on general counselling principles (30) and was guided by the NICE guidelines for young people with mild to moderate depression (31). The behavioural activation physical activity intervention assisted participants in working towards
meeting the Australian guidelines for physical activity (28, 29) via a process of identifying barriers and strengths for engaging in regular exercise and monitoring physical activities. Participants were provided with psycho-education on the relationship between exercise and mood/anxiety symptoms, along with physical activity diaries and pedometers to record and encourage regular activity.

**Outcomes and measures**

The primary outcomes were depression and anxiety symptoms at the end of treatment and the follow-up points, measured by the Beck Depression Inventory-II (BDI-II (32)), Beck Anxiety Inventory (BAI (33)), and Montgomery Åsberg Depression Rating Scale (MADRS (34); observer-rated measure).

**Data analysis**

Primary analyses were conducted on an intent-to-treat basis, including all participants randomised regardless of treatment actually received or withdrawal from the study. Mixed-model repeated measures analyses were used, as this approach enabled the inclusion of participants with missing data, without using inferior techniques such as last observation carried forward (35). For analyses of binary, ordinal and categorical outcomes, non-linear mixed modelling was used.

**Plans for dissemination**

The study protocol has been published in BMC Trials (26) and available on the ANZCTR website. The analysis for the post-treatment results has been completed and a manuscript is being prepared for publication. Plans for further publications
include the reporting of the 6 month and 12 month follow-up assessment data. To date, the results of the post-treatment assessment have been presented at two international conferences (36, 37).

**Results**

Overall, depression scores measured by the MADRS and BDI-II reduced over the course of the trial. A similar reduction was observed with anxiety scores measured by the BAI.

For the comparison between the physical activity group and psycho-education group, the overall interaction of time and treatment arm was significant for the BDI-II. Planned contrasts showed that the physical activity group improved significantly more than the psycho-education group between pre- and post-intervention (see Figure 1). The mean difference in improvement on the BDI-II was 3.76 with an effect size of $d=0.41$. Although the overall time by group interaction for the MADRS was not statistically significant, there was a significant difference between groups in improvement from pre- to post-intervention (see Figure 2). The physical activity group showed a mean improvement of 3.17 points more than the psycho-education group on the MADRS, $d=0.48$. In contrast, the overall time by treatment arm interaction was not significant for the BAI and there were also no significant differences between groups on the change from pre- to post-intervention (see Figure 3).
For the comparison between the PST group compared to supportive counselling, the overall interaction of time and treatment arm was not significant for any of the primary outcomes.

Figure 1. Estimated marginal means and standard errors (±1 SE) for depression (BDI-II) symptoms

Figure 2. Estimated marginal means and standard errors (±1 SE) for depression (MADRS) symptoms
Further research

The results of this study have shown that the young people who received the physical activity intervention reported the greatest improvement in depression symptoms regardless of the type of psychological treatment they received. As these interventions were delivered in the controlled conditions of a trial, further research can explore whether the same effects are found when delivering the intervention in ‘real-world’ settings. The current researchers have recently been awarded an NHMRC Project Grant to enable the investigation of this research question, namely to examine the effects of adding the physical activity intervention into treatment as usual delivered in headspace centres. Additional further research could also examine the mediation effects of physical activity versus a general behavioural activation.
approach. This work would enable us to answer whether the benefit in mood is directly from engagement in physical activity or whether improvements are due to the benefits of the overarching behavioural activation framework used in this study.
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