GUIDED PHYSICAL ACTIVITY FOR DEPRESSION: A RANDOMIZED CONTROLLED TRIAL OF AN INTERNET ADMINISTERED TREATMENT

Morgan Ström och Carl-Johan Uckelstam

Handledare: Per Carlbring, professor
Examinator: Åke Olofsson, professor
Thank you!

Thanks Per Carlbring for your dedication and support throughout the project, from start to finish!

Thanks Peter Hassmén for your expertise on physical activity and depression!

Thanks Lina Aittamaa and Linda Ek, our colleagues in the Progredi Project!

Thanks John Långström and Anders Hagström for your involvement during the first part of this project!

Thanks Keefer Wong and Margery Roberts for your help with the linguistic part of the thesis!

Tack!

Tack Per Carlbring för ditt engagemang och stöd under hela projektet, från början till slut!

Tack Peter Hassmén för din expertis inom området fysisk aktivitet och depression!

Tack Lina Aittamaa och Linda Ek, våra kollegor i Progredi-projektet!

Tack Johan Långström och Anders Hagström för samarbetet under den första delen av projektet!

Tack Keefer Wong och Margery Roberts för er hjälp med den språkliga delen av uppsatsen!
GUIDED PHYSICAL ACTIVITY FOR DEPRESSION: A RANDOMIZED CONTROLLED TRIAL OF AN INTERNET ADMINISTERED TREATMENT

Morgan Ström och Carl-Johan Uckelstam

Physical activity has been shown to be an effective treatment for depression. The aim of this study was to develop and evaluate an Internet-administered self-help treatment for depression, based on physical activity. The structure of the program was planned, relevant literature was collected and the treatment modules were written by the authors. 48 participants with mild to moderate depression, diagnosed using the Structured Clinical Interview for DSM-IV Axis I disorders, were randomized to a treatment or a waiting-list control group. The main outcome measure for depression was the Montgomery-Åsberg Depression Rating Scale: Self Rating Version and physical activity level was measured using the International Physical Activity Questionnaire. The treatment program consisted of nine text modules with therapist guidance. The results showed a significant improvement of depressive symptoms in the treatment group compared to the control, with a moderate effect size ($d = 0.61$). No difference was found between the groups in physical activity level. The program seems to be an effective treatment for depression. The results are discussed along with an evaluation of the benefits and limitations of the program.

Throughout history people have experienced melancholy and loss of interest in activities. Originating in 300 B.C., Hippocrates conceptualized the first clinical description of melancholia, a state we today label as depression. Emil Kraepelin, a German psychiatrist from the ninth century, was first to mention depression in the medical literature. The majority of his description of the disorder is still used by clinicians today (Beck & Alford, 2009).

Most people occasionally feel down or sad in their everyday life. Depression on the other hand is generally diagnosed when absence of positive affects are
accompanied by melancholy or loss of interest in activities for more than two weeks. When people experience this condition without the catalyst of a specific life event, or if the state remains over time, depression is apparent.

Today, the accepted psychiatric term is major depressive disorder (MDD). Distinguishing MDD from “normally” occurring mood changes, remains problematic. The Diagnostic and Statistical Manual of Mental Disorders, fourth edition ([DSM-IV], American Psychiatric Association, 2000) provides a common language and standard criteria for the classification of mental disorders. According to DSM-IV the most typical symptoms of depression, in addition to melancholy and anhedonia, are psychomotor agitation or retardation, weight loss or weight gain, insomnia or hypersomnia, inappropriate guilt, concentration difficulties, fatigue or loss of energy and suicidal ideation (American Psychiatric Association, 2000).

The severity of the depression is typically specified along the continuum: mild, moderate, severe without psychotic feature and severe with psychotic feature depending on the degree of symptoms, and the number of criteria obtained by the patient.

The World Health Organization ([WHO], 2001) predicts that depression will be one of the three most burdensome diseases in the world before 2020. In Sweden depression is already one of the most common diagnosis in primary care clinics, with a lifetime prevalence of 15% for men, and 25% for women (Swedish National Board of Health and Welfare [Socialstyrelsen], 2010). The cost of depression is substantial for the individuals afflicted, and for the society as a whole. The main monetary cost of depression in Sweden are indirect costs due to sick leave and early retirement which has doubled from a total of €1.7 billion in 1997, to €3.5 billion in 2005 (Sobocki, Lekander, Borgström, Ström, & Runeson, 2007).

In conclusion, depression is a condition that continues to influence society and people’s lives in significant ways. It is, therefore, an important task to keep on studying the condition to find new and effective ways for successful treatment.
Treatments for depression

Depression is usually treated with antidepressant medication or psychological therapies (Mead et al., 2009). Depending on the severity of symptoms, Socialstyrelsen recommends different interventions. For severe depression, when the level of function and quality of life is strongly reduced, and the person has great difficulty in accomplishing everyday activities, pharmaceutical treatment with antidepressants is given the highest priority. For mild to moderate depression, variations of psychological treatment are given the highest priority (Swedish National Board of Health and Welfare, 2010).

There is a growing interest for finding alternative treatments to medication and psychological treatments of depression (Mead et al., 2009). Traditional treatments can be both expensive and time consuming (Newman, Erickson, Przeworski, & Dzus, 2003) and may not fit patients’ preferences, attitudes or beliefs (Astin, 1998). Antidepressants have certain drawbacks like adverse side effects, poor adherence and a lag time between starting treatment and mood improvement. Psychological treatments may be avoided by some people because of perceived stigma, even-though these interventions are generally free from side effects (Mead et al., 2009).

Physical activity as a treatment for depression

Since the beginning of the 20th century, a large amount of research has been conducted concerning the effectiveness of physical activity on clinical depression and depressive symptoms. Many studies have found significant antidepressive effects (e.g. Martinsen, Medhus & Sandvik, 1985; Mather et al., 2002; Blumenthal et al., 2007) ranging in size from moderate to large (Mead et al., 2009).

Martinsen, Medhus and Sandvik (1985) found a significantly larger decrease in depressive symptoms measured with Beck Depression Index ([BDI], Beck, Ward, Mendelson, Mock & Erbaugh, 1961), as well as an increase in maximum oxygen uptake for a training group compared to a control group in psychiatric inpatients diagnosed with MDD. The training program consisted of aerobic exercise at 50-70% of maximum aerobic capacity during one hour, three times a week, for nine weeks. The authors concluded that physical exercise has an antidepressant effect for adults up to 60 years of age.

Mather et al., (2002) found antidepressant effects of physical exercise in older people with poorly responsive depressive disorder. After ten weeks with two exercise classes a week, consisting of 45 minutes of endurance, muscle strengthening and stretching activities, a significantly larger amount of the
treatment group responded positively (≥ 30% reduction in depressive symptoms measured with the Hamilton Rating Scale for Depression) compared to the control group. The authors’ conclusion was that “older people with poorly responsive depressive disorder should be encouraged to attend group exercise activities” (Mather et al., 2002, p. 415).

Finally, Blumenthal et al. (2007) compared exercise to pharmacological treatment for depression and found comparable efficacy for both treatments compared to placebo. Participants randomized to supervised as well as unsupervised physical exercise, consisting of three 45-minutes sessions of aerobic exercise in the range 70 – 85% of maximum heart rate reserve per week during 16 weeks, achieved remission rates (45% and 40% respectively) similar to the medication group (47%) and higher than those in the placebo control group (31%).

The findings of these studies and many others indicate that physical exercise has a significant antidepressant effect. However, the majority of studies in this area have important methodological weaknesses. Several recent meta analyses concludes that most randomized controlled trials available do not meet certain criteria for high quality research, such as adequate allocation concealment, blinded assessment of the outcome and intention to treat analysis (Krogh, Nordentoft, Sterne & Lawlor, 2011; Mead et al., 2009; Conn, 2010; Lawlor & Hopker, 2001). In a recent review by the Cochrane foundation, only three studies were found to meet these criteria (Blumenthal et al., 2007; Dunn, Trivedi, Kampert, Clark & Chambliss, 2002; Mather et al. 2002).

The current estimates of the effectiveness of physical activity as a treatment for depression or depressive symptoms are heterogeneous. This could in part be explained by differences in methodological quality. Lawlor and Hopker (2001) pointed out that “lack of concealment, intention to treat analysis and blinding” (p.5) might overestimate the benefits of interventions based on physical exercise. This was supported by the findings of Mead et al. (2009), which showed differences in effect size between high quality studies and the other studies included in the analysis. Using Cohen’s d (Cohen, 1988) and a random effects model for calculating effect size, the standardized mean difference of depressive symptoms compared with control groups, were 0.42 for the high quality trials and 0.82 for all 13 included trials.

There seems to be a consensus that physical exercise is to some degree effective as a treatment for depression. Although, the mechanisms by which physical exercise reduce depressive symptoms is an area for debate. Examples of psychological theories are behavioural activation, sense of achievement, self-determination, self-efficacy, self-esteem, and distraction from depressive
thoughts. The main physiologically based theory is improvement in fitness leading to various biological and chemical changes in the brain and the body (Conn, 2010).

According to Perraton, Kumar and Machotka (2010), the current evidence for level of physical activity in the treatment of depression supports interventions consisting of supervised aerobic exercise of three 30-minute sessions per week at 60-80% of maximum heart rate for at least eight weeks. This conclusion is based on the most common interventions used in 14 randomized controlled studies published between 1979 and 2007. However, there is no evidence to date of a dose-response relationship between physical activity and depression (Kesaniemi et al., 2001). This means that a higher amount of physical activity does not seem to correspond to a larger effect on depressive symptoms.

The global recommendations for physical activity (WHO, 2010) are based on a wider area of research covering other health issues than depression, such as obesity, coronary heart disease, high blood pressure, stroke, diabetes, metabolic syndrome, hip or vertebral fractures, bone-mass density and breast and colon cancer. There is substantial evidence that physical activity reduces all-cause mortality as well as prevalence of previously mentioned conditions (WHO, 2010). In accordance with this research, adults aged 18-64 are recommended to "...do at least 150 minutes of moderate-intensity aerobic physical activity throughout the week or do at least 75 minutes of vigorous-intensity aerobic physical activity throughout the week or an equivalent combination of moderate- and vigorous-intensity activity." (WHO, 2010, p. 26).

In conclusion, physical exercise seems to be effective as a treatment for depression and depressive symptoms. However, the estimated effect size remain imprecise and the mechanisms of the effect are unknown. More high quality studies are needed for a good estimation of effect size and to investigate the mechanisms behind improvement.

Theoretical models for physical activity and depression

There are many psychological theories about clinical treatments of depression, ranging from psychodynamic conceptualizations of internalized aggression to behavioural accounts of avoidance and lack of positive reinforcement. There are also many theories about supporting physical activity, including behavior change models and motivation. However, these theories are seldom combined into one effective intervention, treating depression and increasing physical activity.
Theories used in this study are collected from sound scientific research on depression, behavioral change and motivation. They include behavioral activation and the spiral model for depression, self-determination theory, self-efficacy, stages of change, acceptance and commitment therapy and motivational interviewing (Hassmén & Hassmén, 2005; Faskunger, 2004; Haase, Taylor, Fox, Thorp & Lewis, 2010; Hemmingsson, Page, Fox, & Rössner, 2001; Ryan & Deci, 2000; Spencer, Adams, Malone, Roy, & Yost, 2006).

**Behavioural activation and the spiral model for depression**

Behavioural activation (BA), as a treatment for depression, is a third generation behavior therapy. As such, it is derived from the conceptual framework of Skinnerian clinical behavior analysis. It is focused on helping depressed individuals to “reengage in their lives through focused activation strategies” (Jacobson, Martell & Dimidjian, 2001, p. 255). The main strategy, activation scheduling, teaches patients to monitor their mood and daily activities and to increase the number of pleasant activities. This is based on research showing that depressed people find fewer activities pleasant, engage less frequently in pleasant activity and therefore, receive less positive reinforcement than non-depressed people (Cuijpers, van Straten & Warmerdam, 2007).

The so called “spiral model” is a way of explaining depression through one specific behaviour, physical activity (Haase, Taylor, Fox, Thorp & Lewis, 2010). The model was developed by Haase et al (2010) and constitutes the idea that feeling low or down, often leads to lowered motivation to do things that are fun, pleasurable or result in a sense of achievement. The reduced activity results in fatigue and tiredness, which leads to more depressive symptoms and lower motivation for activation, which completes a downward spiral. Physical activity may be a way to increase activity and disrupt the effects of this degenerating spiral.

**Self-Determination Theory**

Activation scheduling depends on the individual’s motivation for physical activity and behavior change. Self-Determination Theory (SDT) is an approach that distinguishes among different types of motivation. Autonomous motivation for instance, occurs when a person fully endorses a behavior and experiences volition and choice. Controlled motivation, on the other hand, occurs when a person feels forced or pressured into the behavior (Deci & Ryan, 1985). For long-lasting behavior change to occur, research shows that autonomous motivation is superior to controlled forms of motivation (Mata et al., 2009; Wilson, Rodgers, Fraser, & Murray, 2004).
SDT proposes that individuals have three basic psychological needs which must be satisfied in order for autonomous motivation to develop, these needs are *competence, autonomy and relatedness* (Ryan & Deci, 2000; Deci & Ryan, 2000).

Competence can be viewed as the individual's feeling of being capable of obtaining a desired behavioural outcome. Within the exercise context, this may, for example, be accomplished by meeting goals, or to feel comfortable in an exercise setting. Autonomy relates to behaving in accordance with abiding values and interests, and to make decisions that are within the individual's control. In regards to physical activity this may, for example, be obtained by facilitating belief, that successful behavioural change arises from personal drive, and by letting the individual independently choose which type of physical activity to engage in. Relatedness incorporates feeling of being cared for, connected to and a sense of belonging with others (Ryan & Deci, 2000).

Research suggests that autonomous motivation regarding physical activity is related to increased physical self-esteem (Wilson & Rodgers, 2003), more positive attitudes towards exercise (Wilson et al., 2004), and increased participation and devotion for physical activity (Chatzisarantis & Hagger, 2009). Autonomous motivation for exercise has also shown to be connected to greater self-efficacy for becoming active (Sweet et al., 2009) and to long-term behavioural change (Mata et al., 2009; Silva et al., 2010).

**Self-efficacy**

One of the most regularly mentioned psychological mediator of successful behavioural change is self-efficacy (McAuley, Lox, & Duncan, 1993). Self-efficacy relates to the individual's beliefs in his or her capabilities to perform necessary actions to satisfy situational demands. Self-efficacy is theorized to influence the activities that an individual chooses to approach, the effort spent on such activities, and the degree of persistence demonstrated in the face of failure. Self-efficacy is highly situational and one person can for example have high self-efficacy for cycling but at the same time low self-efficacy for weight training (McAuley, Lox, & Duncan, 1993; Bandura, 1986).

Self-efficacy is increased by success, and when a sense of expertise and competence is developed. Research suggests that self-efficacy, in regards to physical activity, is particularly important in the early phases of behavior change, and less important as physical activity becomes less psychologically demanding (McAuley, Lox, & Duncan, 1993).
Self-monitoring and progressive goal setting are ways to increase self-efficacy for physical activity (Biddle & Fox, 1998; Perri, McAdoo, Lauer, McAllister, Yanzey, 1986). Self-monitoring can be done in several ways, for example by using electronic pedometers where the number of steps taken can easily be monitored. Used in a combination of record keeping with a diary or calendar, pedometers can be used in an effective way to increase self-efficacy for physical activity. Besides self-monitoring however, improvement of self-efficacy can be achieved through autonomous achievement of personally directed goals (Tudor-Locke, 2002). For efficient goal setting, the SMART model can be applied. This is an acronym for Specific, Measurable, Attainable, Relevant and Time bound, which are criteria that when met, make goals clearly defined and usable (Hassmén & Hassmén, 2005).

Stages of change

The transtheoretical model (TTM) is a widely used theory describing how individuals progress through different stages when trying to change health behaviours (Prochaska & DiClemente, 1983). The model was first developed in the 1980’s when studying individuals who attempted to stop smoking. The theory suggests that individuals move through five stages of change when trying to change health related behaviour:

- **Precontemplation**: In this stage the individual has no intention to change in the near future, and is unaware of problems associated with continuing the behaviour he or she is trying to change.
- **Contemplation**: The individual is aware of problems associated with the prevailing behavior and is seriously thinking about overcoming it. However, he or she has not yet made a commitment to take action.
- **Preparation**: Individuals in this stage are intending to take action in the next month and have unsuccessfully taken action in the past year.
- **Action**: In this stage the individual modifies his or her behaviour, experiences, or environment in order to overcome the problem. This stage requires considerable commitment of time and energy.
- **Maintenance**: This is a stage where the individual works to prevent relapse and strengthen changes attained during action.

Movement through these stages could be both linear and cyclical because individuals often tend to make several attempts to overcome their difficulties before long lasting behaviour change is accomplished (Kalling, 2008).

There is a growing body of evidence that TTM could be applied to enhancement of physical activity by using stage-matched interventions. The concept of this
way of using the theory is to develop interventions that are appropriate for the individuals’ readiness of change as a way to enable optimal forward stage progression (Spencer et al., 2006). Some components for interventions in the early stages of change is, for example, decisional balance exercises for exploring pros and cons for change, and self-efficacy development, as a way to build a confidence in the ability to change (Kalling, 1997).

There is still an on going debate of the prospective value of the transtheoretical model (West, 2005). Evidence for the validity of TTM as applied to exercise, is still mixed, but two review articles propose that the transtheoretical model can be applied to the enhancement of physical activity (Spencer, Adams, Malone, Roy & Yost, 2006).

**Acceptance and Commitment Therapy (ACT)**

Acceptance and Commitment Therapy can be considered a third generation behaviour therapy with similar theoretical underpinnings to BA. The main difference is the application of Relational Frame Theory (RTF), a behavioural account of human cognition and language (Hayes, Luoma, Bond, Masuda & Lillis, 2006). It uses acceptance and mindfulness strategies, in combination with commitment and behavior change strategies, to increase psychological flexibility in patients. An example of an exercise incorporating both acceptance and commitment is the valued direction exercise were the patient chooses behaviours in accordance with his or hers valued direction.

**Motivational Interviewing (MI)**

MI is a patient centred and flexible method, used to explore and resolve ambivalence about different health related behaviours as a way to help participants identify their own motivation for making changes (Rollnic & Miller, 1995). MI strategies have been associated with higher levels of adherence and motivation for physical activity in a range of populations (Hardcastle, Taylor, Bailey, & Castle, 2008; Markland, 1999; Sevick et al., 2007).

**Internet delivered treatment**

With the advancement of communication technologies, new ways of providing and delivering psychological treatments have emerged. The Internet has made it possible to reach people over great distances and therefore to provide psychological interventions to a vast number of patients at a low cost due to shorter treatment time per person (Titov et al, 2009). Internet delivered treatments also have the opportunity to increase accessibility to patients in remote geographical locations and to make support available for people who
would not otherwise seek care (Andersson & Carlbring, 2003). Further-more, Internet delivered treatments have the possibility to give patients quick feedback and presentation of material on a step-by-step basis.

Studies of Internet delivered treatments vary in the amount of contact with a therapist ranging from completely self-administered therapy to therapist-administered treatments involving regular contact with a therapist. Research has shown that self-help programs in which support is provided are more effective than programs without support (Andersson, 2006; Andersson & Cuijpers, 2009).

Currently, several studies have investigated the effects of Internet delivered treatment for depression (e.g. Andersson & Cuijpers, 2009; Newman, Szkodny, Llera, & Przeworski, 2011). A large part of these studies have cognitive behavior therapy (CBT) as theoretical framework. The effects of Internet-delivered CBT were summarized in a meta-analysis in 2007 showing a moderate between-group effect size of Cohen's $d = 0.40$ (Spek et al., 2007). Andersson & Cuijpers (2009) replicated the effects in their meta-analysis but found a significant difference between supported ($d = 0.61$) and unsupported ($d = 0.25$) treatments.

It is however important, to consider that many of the studies included in these meta-analyses are limited by various methodological problems. For example, few studies included follow-up assessments, which make it problematic to predict long-term effects of the treatment. Further-more, few studies examined whether the interventions led to clinically significant change at post-therapy. This limits the conclusions that may be drawn of the efficacy of the treatments (Newman, Szkodny, Llera, & Przeworski, 2011).

In a study by Andersson et al. (2005), 117 participants were recruited for an eight week internet delivered self-help treatment based upon a CBT concept. Participants were diagnosed with MDD and were randomized to either an active treatment condition or to participate in a discussion group. The participants had a mean score on the Montgomery-Åsberg Depression Rating Scale ([MADRS-S] Fantino & Moore, 2009; Holländare, Andersson & Engström, 2010) of 20 and a BDI mean score of 21 at pre-treatment, indicating mild-to-moderate depression. Analyses of variance at post treatment showed significant interaction effects for both MADRS-S ($p<0.01$) and BDI ($p<0.001$) between the groups, and a corresponding effect size of Cohen's $d = 0.79$ (Cohen, 1988) for MADRS-S and $d = 0.94$ for BDI. There was found no statistically significant interaction effect on the Quality of Life Inventory ([QOLI] Frisch, Cornell, Villanueva & Retzlaff, 1992) mirrored by a low effect size of 0.32.
In accordance with this, Vernmark et al. (2010) examined two internet delivered self-help treatments based upon a CBT framework. Both treatments lasted for eight weeks but differed in the amount of therapist contact. 88 persons with diagnosed depression were randomly assigned to the three groups; “E-mail” (the one with most therapist contact), “Self-help” or a waiting-list control. At pre-treatment, all groups had a MADRS-S mean score of 21 and a BDI mean score of 22, indicating moderate depression. At post-treatment, significant interaction effects were found on BDI and MADRS-S for the “E-mail” group but not for the “Self-help” group with effect sizes of Cohen’s $d = 0.96$ (BDI) and $d = 0.82$ (MADRS-S) for the “E-mail” group, and $d = 0.56$ (BDI) and $d = 0.36$ (MADRS-S) for the “Self-help” group.

The study’s aim

Due to the severe suffering of the people afflicted, and the vast monetary costs for depression, new and effective treatments are still required. Among the guidelines for treatment of depression are Internet delivered cognitive behaviour therapy and physical activity (Swedish National Board of Health and Welfare, 2010). Currently, no study has examined the effects of physical activity administered as a guided self-help treatment over the Internet, as a way to treat mild to moderate depression. The development of a treatment, combining the pragmatic approach of physical exercise and the cost-effectiveness and accessibility of Internet delivered treatment, is therefore an interesting approach.

The purpose of the present study was to develop and evaluate a treatment for depression based on physical exercise administered via the Internet. The treatment programme was intended to decrease depressive symptoms in the subjects and to motivate them to raise their level of physical exercise. A treatment group was compared to a waiting-list condition.

Through this randomized controlled trial (RCT), conducted with allocation concealment, intention to treat analysis and blinded outcome assessment, we hope to contribute to the present knowledge of the effects of physical exercise on mild-to-moderate MDD.

Hypotheses

1. Participants in the treatment condition will have reduced depressive symptoms compared to the control, measured with the MADRS-S (Fantino & Moore, 2009; Holländare, Andersson & Engström, 2010) and the BDI-II (Beck, Steer & Brown, 2006).
2. The treatment condition will have reduced anxiety symptoms compared to the control, measured with the Beck Anxiety Inventory ([BAI] Beck & Steer, 2009).
3. The treatment condition will have increased levels of physical activity compared to the control, measured with the International Physical Activity Questionnaire (Craig et al., 2003).
4. There will be a correlation between reduction in depressive symptoms and increased physical activity for all subjects.
5. Participants in the treatment condition will have increased quality of life compared to the control, measured with the QOLI (Frisch, Cornell, Villanueva & Retzlaff, 1992)

Method

This study was a randomized, waiting list control group 9-week trial of an Internet administered treatment programme based on physical exercise for MDD.

Recruitment

The project was announced on a website ([www.progredi.nu] with information about the study and instructions on how to register for participation. The project’s website was advertised in a major newspaper (Dagens Nyheter) and on Google search. A portal website, where people continuously register their interest for participation in Internet administered treatments for psychological disorders, ([www.studie.nu], was also linked to the project’s website. The study was open for registration between January and February 2012. To register for participation, people were asked to answer an online survey collecting contact information, demographic data, screening measures and pre-measurement data.

Selection criteria

The participants included in the study met the criteria for MDD according to the international classification system, Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV). Subjects with mild to moderate depression and a low level of physical exercise were preferred in accordance with this study’s aims. Exclusion was based on the following criteria: subclinical depressive symptoms, severe depressive symptoms, dysthymia as a primary diagnosis, high suicide risk, high levels of physical activity, recent changes in medication and somatic illness making physical exercise inappropriate.
Eligibility screening

The screening process started with the online survey that participants filled in to register for participation in the study. Among the questions were several self-rating inventories for depressive symptoms, anxiety and level of physical activity. MADRS-S (Fantino & Moore, 2009; Holländare, Andersson & Engström, 2010) was used to screen for subclinical symptoms (cut-off score <15) and severe depression (cut-off score >30). The ninth question in this inventory, which measures suicidal thoughts, was used to screen for suicide risk (<4). To complement MADRS-S, BDI-II (Beck, Steer & Brown, 2006) was also used as a screening tool for depression with cut-off scores 14 and 28. To screen for anxiety, BAI (Beck & Steer, 2009) was used. IPAQ (Craig et al., 2003) was included to get estimates of participants’ level of physical activity and QOLI (Frisch, Cornell, Villanueva & Retzlaff, 1992) to measure quality of life. Finally, the survey contained questions collecting demographic data. After this initial self-assessment, 56 persons were excluded due to the criteria stated in the section above.

The remaining 89 subjects were called and interviewed, using questions from the part on mood disorders in the Structured Clinical Interview for DSM-IV: Clinical version ([SCID-I-CV] First, Gibbon, Spitzer & Williams, 1999). Four students did this during their last semester of the psychology program with supervision by a professor in clinical psychology. When all subjects had been interviewed, a group conference was held to discuss inclusion and exclusion based on the information collected from the online survey and the clinical interviews. Present at the conference were the four students, the professor and a medical doctor. 41 people were excluded at this stage, and the remaining 48 were included into the study.

Intervention

The treatment used in this study was a guided self-help program administered over the Internet. The program consisted of nine text modules developed by the authors, comprising of 72 pages in total. Relevant literature was examined to find theories and strategies that could best guide the design of the treatment program (Hassmén & Hassmén, 2005; Faskunger, 2004; Haase, Taylor, Fox, Thorp & Lewis, 2010; Hemmingsson, Page, Fox, & Rössner, 2001; Ryan & Deci, 2000; Spencer, Adams, Malone, Roy, & Yost, 2006). Theoretical frameworks used in the program were behavioural activation and the spiral model for depression, self-determination theory, self-efficacy, stages of change and acceptance and commitment therapy. Participants were given one text module every Monday during nine weeks, and at the end of each week the authors gave feedback on home assignments included in the modules.
The feedback was based on motivational interviewing principles. Most material was transmitted via a highly secure web-based system for electronic communication, “kontakthanerings-systemet” (KHS). Some material, such as the pedometer given participants in the treatment condition and forms of consent for the Personal Data Act (SFS 1998:204), was sent using physical mail.

The modules consisted, in a broad sense, of self-help text about how to become more physically active, in addition to, weekly assignments. See Appendix I for an overview of the contents in the treatment program.

The program was written by the authors partly in advance of the treatment and partly during the nine weeks of the treatment. Some of the core principles when developing the program were to:

1. Maximize the likelihood for participants to increase and maintain physical activity.
2. Maximize the likelihood of subjects remaining engaged in the program.
3. Focus on the participant’s preferences and needs, taking particular notice of the challenges faced by people with depression.
4. Promote physical activity in a broad sense in accordance with the WHO’s guidelines for physical activity (2010), including all type of activity in everyday life.
5. Increase self-efficacy for physical activity.
6. Help subjects to master challenges faced with when trying to get more active.

Participants

The study included 48 subjects. The participants were randomly allocated to two conditions, intervention or control, by a person independent of the research group, using a random number service on the Internet (www.random.org). As evident from Table 1, the two groups had no significant differences in demographic data for sex $x^2 = 0.0, p = 1.0$, age $t_{16} = -0.25, p = .80$, marital status $x^2 = 2.92, p = .40$, highest educational level $x^2 = 4.12, p = .39$, medication, $x^2 = 2.28, p = .32$ and psychotherapy $x^2 = 0.0, p = 1.0$. 
Table 1. Demographic description of the participants at pre-treatment

<table>
<thead>
<tr>
<th></th>
<th>Treatment (n=24)</th>
<th>Control (n=24)</th>
<th>Total (n=48)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>20 (83.3%)</td>
<td>20 (83.3%)</td>
<td>40 (83.3%)</td>
</tr>
<tr>
<td>Male</td>
<td>4 (16.7%)</td>
<td>4 (16.7%)</td>
<td>8 (16.7%)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>48.8 (12.7)</td>
<td>49.6 (8.7)</td>
<td>49.2 (10.7)</td>
</tr>
<tr>
<td>Min-Max</td>
<td>24-67</td>
<td>35-65</td>
<td>24-67</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/Living together</td>
<td>13 (54.2%)</td>
<td>9 (37.5%)</td>
<td>22 (45.8%)</td>
</tr>
<tr>
<td>Living apart</td>
<td>2 (8.3%)</td>
<td>2 (8.3%)</td>
<td>4 (8.3%)</td>
</tr>
<tr>
<td>Single</td>
<td>8 (33.3%)</td>
<td>13 (54.2%)</td>
<td>21 (43.3%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (4.2%)</td>
<td>0 (0%)</td>
<td>1 (2.1%)</td>
</tr>
<tr>
<td><strong>Highest educational level</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compulsory school</td>
<td>1 (4.2%)</td>
<td>0 (0%)</td>
<td>1 (2.1%)</td>
</tr>
<tr>
<td>Secondary school</td>
<td>3 (12.5%)</td>
<td>3 (12.5%)</td>
<td>6 (12.5%)</td>
</tr>
<tr>
<td>Vocational school</td>
<td>0 (0%)</td>
<td>3 (12.5%)</td>
<td>3 (6.3%)</td>
</tr>
<tr>
<td>College/university (on-going)</td>
<td>2 (8.3%)</td>
<td>2 (8.3%)</td>
<td>4 (8.3%)</td>
</tr>
<tr>
<td>College/university (compl.)</td>
<td>18 (75%)</td>
<td>16 (66.7%)</td>
<td>34 (70.8%)</td>
</tr>
<tr>
<td><strong>Medication</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>10 (41.7%)</td>
<td>14 (58.3%)</td>
<td>24 (50.0%)</td>
</tr>
<tr>
<td>Earlier</td>
<td>11 (45.8%)</td>
<td>6 (25.0%)</td>
<td>17 (35.4%)</td>
</tr>
<tr>
<td>Present</td>
<td>3 (12.5%)</td>
<td>4 (16.7%)</td>
<td>7 (14.6%)</td>
</tr>
<tr>
<td><strong>Psychotherapy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>9 (37.5%)</td>
<td>9 (37.5%)</td>
<td>18 (37.5%)</td>
</tr>
<tr>
<td>Earlier</td>
<td>15 (62.5%)</td>
<td>15 (62.5%)</td>
<td>30 (62.5%)</td>
</tr>
<tr>
<td>Present</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

The patient flow through the study is presented in Figure 1. People excluded because of severe depression, high suicide risk and high level of physical exercise were contacted and encouraged to seek treatment in their communities. People excluded because of minimal depression were given advice on self-treatment.
159 applicants registered their interest in the study

45 answered the online screening questionnaires

Excluded (n=56)
- 4 were not reached for a telephone interview
- 3 completed screening too late
- 13 were excluded due to high scores on MADRS-S (>30)
- 1 was excluded due to high suicide risk on item 9 on MADRS-S (<5)
- 18 were excluded due to low scores on MADRS-S (<15)
- 17 were excluded due to high level of physical exercise

Excluded (n=41)
- 4 were excluded due to somatic illness
- 5 were excluded due to imminently making changes in pharmacological treatment of their mental ill health
- 9 were excluded due to being assessed as having a severe mental disorder rendering them unlikely to benefit from the materials
- 10 were excluded due to exhibiting subclinical symptoms
- 13 were excluded due to high level of physical exercise

89 were subjected to telephone interviews

48 were included into the study

Excluded (n=14)
- 4 did not answer any of the screening questions
- 10 started but did not finish screening process

24 were included into the control condition

24 were randomized to the control condition

24 were randomized to the treatment condition

<table>
<thead>
<tr>
<th>Module</th>
<th>Completed</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module 1</td>
<td>24</td>
<td>100.0%</td>
</tr>
<tr>
<td>Module 2</td>
<td>21</td>
<td>87.5%</td>
</tr>
<tr>
<td>Module 3</td>
<td>19</td>
<td>79.2%</td>
</tr>
<tr>
<td>Module 4</td>
<td>18</td>
<td>75.0%</td>
</tr>
<tr>
<td>Module 5</td>
<td>17</td>
<td>70.8%</td>
</tr>
<tr>
<td>Module 6</td>
<td>15</td>
<td>62.5%</td>
</tr>
<tr>
<td>Module 7</td>
<td>14</td>
<td>58.3%</td>
</tr>
<tr>
<td>Module 8</td>
<td>14</td>
<td>58.3%</td>
</tr>
<tr>
<td>Module 9</td>
<td>14</td>
<td>58.3%</td>
</tr>
</tbody>
</table>

48 completed post testing

Figure 1. The patient flow through the study.
Ethical considerations

Participation in the present study was voluntary and subjects were free to end their commitment at any time. Participants were informed of the self-help nature of the treatments provided and that any improvement required engagement from their part.

The following ethical risks were identified prior to the study: that participants in need of specialized medical investigations or severely depressed individuals may be included in the study. At the slightest notion of unclear etiology, participants were encouraged to seek medical attention at home. Severely depressed and suicide prone individuals were excluded, based on self-assessment scores and a clinical interview by telephone. The people excluded from the study were expected to perceive this negatively. They were therefore given recommendations on how and where to seek alternative treatment in their community and, when deemed appropriate, given a list of self-help literature.

Participants were informed that they would be randomly allocated to one of the two conditions, the treatment group and the waiting list control group. The former were given the intervention investigated in the present study, starting in February 2012, and the latter were given a psychodynamic-oriented internet-administered treatment, starting in April 2012. All subjects were offered to continuously contact the research group by encrypted e-mail to ask questions.

Another risk identified was the deterioration of people randomly assigned to the waiting list. To monitor their symptoms and get early indications if somebody started to feel worse, all participants in the study were asked to answer MADRS-S weekly. In this way the research group had the possibility to contact deteriorating subjects and encourage them to seek treatment in their community.

To protect participants’ identities, all data has been encoded. All information has been and will continue to be kept strictly confidential and in accordance with the Personal Data Act (SFS 1998:204). Each participant was given a code used to identify the individual during the study. Any document connecting the individual to the code is kept locked in a safe deposit box by the project manager at Umeå University. No individual data is traceable in this scientific report.

The study was examined and approved by the regional ethical committee (Etikprövningsnämnden) in Umeå during May 2011.
Outcome measures

The main outcome measure on depression and depressive symptoms used in this study was the MADRS-S (Fantino & Moore, 2009; Holländare, Andersson & Engström, 2010). Participants in both conditions answered this self-rating scale pre- and post-treatment. BDI-II (Beck, Steer & Brown, 2006) was used as a secondary measure on depression, administered at pre and post-treatment. For evaluating changes in anxiety, physical activity and quality of life, BAI (Beck & Steer, 2009), IPAQ (Craig et al., 2003) and QOLI (Frisch, Cornell, Villanueva & Retzlaff, 1992) were administered during pre- and post-treatment testing.

Materials

Montgomery-Åsberg Depression Rating Scale: Self Rating Version (MADRS-S)

This instrument is a self-rating inventory of depressive symptoms, consisting of nine questions in the areas of sleep, mood, concentration, appetite, anxiety, initiative, emotional involvement, pessimism and suicidal thoughts. Each question can be scored from 0-6 where higher scores indicate more serious symptoms. Its primary use is to detect changes in depressive behaviour and thought (Fantino & Moore, 2009; Holländare, Andersson & Engström, 2010). An overall score of between 15 and 30 is generally considered to indicate mild to moderate depression (Carlbring, 2012 May 7).

MADRS-S was developed from the original clinician’s version of MADRS, which had ten items, a high inter-rater reliability and a significant correlation with the Hamilton Rating Scale for depression, indicating a satisfactory criterion validity (Montgomery & Åsberg, 1979). MADRS-S has recently demonstrated a satisfactory internal consistency of Cronbach’s α = .84 and a moderate correlation with the original MADRS, making it a useful instrument for evaluating MDD (Fantino & Moore, 2009). The psychometric properties of the Internet version and the paper-and-pencil version of the instrument have proved to be equivalent (Holländare, Andersson & Engström, 2010).

Beck Depression Inventory: Second Version (BDI-II)

BDI-II is a commonly used self-assessment depression rating scale. It is a revised version of the original BDI (Beck, Ward, Mendelson, Mock & Erbaugh, 1961) and it is designed to measure changes in depressive symptoms in both clinical and research settings. Symptoms measured by the BDI-II include mood, pessimism, self-loathing, guilt, irritability, social withdrawal and suicidal thoughts. The instrument consists of 21 items in which symptoms are rated on a four-point
scale from 0 to 3, where high scores correspond to more severe levels of depression. A total score of between 0 and 13 is interpreted as minimal depression, scores between 14 and 19 as mild depression, and scores between 20 and 28 as moderate depression. The threshold for major depression is 29 and the maximum score for the BDI-II is 63 (Beck, Steer & Brown, 2006).

Research on the instrument has shown high internal consistencies based on American and Norwegian data on psychiatric patients and normal populations (Cronbach’s α between .86 and .93). The test-retest reliability is satisfactory with values of Pearson’s $r = .93$ in American psychiatric patients and $r = .77$ in Norwegian students. Data confirming the convergent and discriminant validity of the BDI-II has also been collected and evaluated (Beck, Steer & Brown, 2006). Finally, the psychometric properties of the instrument has been proved to remain intact when administered via the Internet, compared to the standard paper-and-pencil version (Holländare, Andersson & Engström, 2010).

**Beck Anxiety Inventory (BAI)**

BAI is a self-assessment inventory consisting of 21 items designed to measure the prevalence of anxiety symptoms during the last week. Each item is scored on a four-point scale from 0 to 3, with a maximum score of 63. A total score of 0-7 is interpreted as minimal anxiety, 8-15 as mild anxiety, 16-25 as moderate anxiety and 26-63 as severe anxiety (Beck & Steer, 2009).

The test-retest reliability of the BAI with one week between measurements has been calculated to a value of Pearson’s $r = .75$ in American and Norwegian populations. The internal consistency is high with values of Cronbach’s α ranging from .88 to .94. Data confirming the convergent and discriminant validity of the BDI-II has also been collected and evaluated (Beck & Steer, 2009).

**The International Physical Activity Questionnaire (IPAQ)**

The IPAQ is a self-report instrument designed to measure physical activity and inactivity in order to obtain comparable data on health-related physical activity (Craig et al., 2003). The IPAQ is available in a long and a short version, covering the past 3 or 7 days. In this study the 7-day version was used.

Activities measured by IPAQ are divided into three categories: walking, moderate intensity activities and vigorous intensity activities. Rating these categories by duration (in minutes) and frequency (in days) gives a total score of the subject’s physical activity. The score is calculated using Metabolic Equivalent of Task (MET) where walking = 3.3 MET’s, moderate intensity = 4.0 MET’s and vigorous intensity = 8.0 MET’s. To calculate the total score, presented in MET-
minutes/week, the products of the frequency, duration and MET value of each domain are added together. A total score of 1500, based on vigorous activities during at least three days, or 3000, based on a combination of activities during seven days, is labelled “high” level of physical activity. A total score of 600, based on a combination of activities during five days, or five days with 30 minutes of walking/moderate activity or three days with 20 minutes of vigorous activities is considered “moderate”. Finally, when none of the criteria stated above are met, the level of physical activity is classified as “low” (International Physical Activity Questionnaire, 2005).

Reliability and validity for the IPAQ was calculated using data from 12 countries collected between 1997 and 1998 (Craig et al., 2003). Test-retest repeatability within a week clustered around a value of Spearman’s ρ = .8 and the median value of the criterion validity was ρ = .3. These results were concluded to be acceptable for measuring physical activity in different arenas and in different languages.

In a Swedish setting, the criterion validity of the 7-day version of the IPAQ was tested by correlating the self-rated level of physical activity with measurements from an accelerometer (Ekelund et al., 2006). The correlation was significant (r = .34, p < .001) which was interpreted as evidence for an acceptable criterion validity for use in Swedish adults. However, the self-reported time spent on physical activity was significantly overestimated by the IPAQ.

Quality of Life Inventory (QOLI)

The self-rating inventory QOLI measures subject’s perceived quality of life. This instrument consists of 16 items covering 16 areas likely to contribute to satisfaction with life, such as work, love and play (Frisch, Cornell, Villanueva, & Retzlaff, 1992).

The respondents answer the questions from two perspectives; the importance of each area (rating from 0 to 2) and how satisfied the respondents are with their situation in this area (rating from -3 to 3). The first rating is multiplied with the second for every area, and the products are added together and then divided by the number of areas not rated unimportant (0) for a total score. The reason for this calculation is to give important areas more impact and to exclude areas that have no importance. The total score can vary between -6 and 6 and the scale is reported to have a value of Cronbach’s α ranging from .77 to .89 for internal consistency and a test-retest reliability of Pearson’s r ranging from .80 to .91 (Frisch, Cornell, Villanueva, & Retzlaff, 1992).
Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders: fourth edition (DSM-IV) Axis I Disorders: Clinical Version (SCID-I-CV)

The SCID-I is a semi-structured clinical interview manual designed to facilitate DSM-IV diagnoses. It provides a system for conducting clinical interviews that allow for both prerequisite and spontaneous questions to be asked during the assessment. The interviewer is guided by the structure to ensure that all criteria are accounted for and how to continue the inquiry when criteria are not met (First, Gibbon, Spitzer & Williams, 1999).

The SCID comes in two different versions; the SCID-I-CV which is used for clinical settings and the SCID-I-RV which is designed for research use. One key aspect of both versions of the SCID-I is that they aspire to include a multi-axial assessment that mimics that of DSM-IV. However, axis-II diagnoses are not covered in the two versions of SCID-I, which instead are covered in a separately designed instrument called SCID-II (First, Gibbon, Spitzer & Williams, 1999). In this study the SCID-I-CV was used.

Statistical analysis

The data was analyzed using Statistical Package for Social Sciences (SPSS) version 17.0. Significance testing of group differences regarding demographic data and pre-treatment measurements was conducted using independent t-tests and chi-2 test (for nominal data).

Differences between-groups regarding pre- and post-measurements on self-report measures (MADRS-S, BDI, BAI, QOLI, IPAQ) were tested with a two-way mixed analysis of variance (ANOVA) with one group- and one time factor. The main outcome measure for depressive symptoms chosen beforehand for this study was MADRS-S.

Between groups effect sizes were calculated at post-treatment using Cohens’s \( d \) where a between groups effect size of \( d > 0.20 \) is considered small, \( d > 0.50 \) medium, and \( d > 0.80 \) large. Within groups effect sizes were calculated using data from pre- and post-treatment measurements (Cohen, 1988).

The results were analyzed with an intention to treat principle. Hence, all randomized participants were included in the post-test regardless if they had completed the treatment or not. 58% of the participants completed all modules in the treatment program. The response rate for all outcome measures was 100% (48 of 48). For the treatment evaluation, the response rate was 58% (14 of 24).
Subjects who changed their medication or began psychological treatment during the study were treated as unchanged (Treatment n = 1, control n = 3). These subjects were included in the statistical analysis using data from the pre-treatment testing carried forward to post-testing (to control for effects from other treatments). Two subjects gave inadequate answers to IPAQ in the pre-testing and were therefore excluded from the analysis on that measurement.

Results

All groups were equal at pre-treatment on MADRS-S, BDI, BAI, IPAQ and QOLI with all t < 0.065 and p > .39.

At pre-treatment, 27% of the participants in the control-group were, according to IPAQ, considered as having a low level of physical activity, 64% as having a moderate and 9% as having a high level of physical activity. In the treatment-group, the percentages were 50%, 46% and 4% respectively.

As evident from Table 2, the treatment condition was superior to the control on both measures of depression (MADRS-S & BDI-II) with significant interactions and medium effect sizes. Results from the main outcome measure, MADRS-S, is presented in Figure 2. No significant differences were found between the groups on measures of anxiety (BAI), quality of life (QOLI) and physical activity (IPAQ). There was no significant correlation between amount of physical activity and depressive symptoms (Spearman’s ρ = .006, p = .49).

Both groups achieved significant decreases in depressive symptoms and anxiety and increases in quality of life and physical activity during the study (p < .01).
Figure 2. Mean scores of MADRS-S for the two groups at pre- and post- treatment with confidence intervals (CI) drawn such that non-overlap indicates a significant between subjects difference at $\alpha = .05$ (Baguley, 2012).

Adherence

10 participants did not complete all modules in the treatment program (42 %). 5 did not complete module 3, and all participants who reached module 7 completed the program (see Figure 1).

Some reasons given for not completing all modules, were that participants believed they did not have sufficient time for physical activity, the program was perceived as not effective, or that changes in life events or sickness made it impossible for participants to complete the program. Some participants ended the program without giving any reason for termination.
Table 2. Results at pre- and post- treatment for measures of depression, anxiety, physical activity and quality of life

<table>
<thead>
<tr>
<th>Time</th>
<th>Treatment (n=24)</th>
<th>Control (n=24)</th>
<th>ANOVA</th>
<th>Between groups effect size</th>
<th>Within groups effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M (SD)</td>
<td>M (SD)</td>
<td>F</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Montgomery-Åsberg Depression Rating Scale: Self Rated Version (MADRS-S)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>23.54 (4.39)</td>
<td>23.92 (3.87)</td>
<td>G: 3.02</td>
<td>0.61</td>
<td>Tx: 1.39</td>
</tr>
<tr>
<td>Post</td>
<td>15.71 (7.54)</td>
<td>20.38 (7.87)</td>
<td>T: 29.82***</td>
<td>I: 4.24*</td>
<td>C: 0.79</td>
</tr>
<tr>
<td></td>
<td>Beck Depression Inventory: Second version (BDI-II)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>26.92 (9.30)</td>
<td>28.25 (7.08)</td>
<td>G: 2.52</td>
<td>0.68</td>
<td>Tx: 0.88</td>
</tr>
<tr>
<td>Post</td>
<td>17.88 (11.30)</td>
<td>24.04 (6.86)</td>
<td>T: 48.77***</td>
<td>I: 6.49*</td>
<td>C: 0.60</td>
</tr>
<tr>
<td></td>
<td>Beck Anxiety Inventory (BAI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>15.50 (7.96)</td>
<td>15.71 (6.53)</td>
<td>G: 0.08</td>
<td>0.14</td>
<td>Tx: 0.36</td>
</tr>
<tr>
<td>Post</td>
<td>12.92 (6.36)</td>
<td>13.71 (5.27)</td>
<td>T: 9.29**</td>
<td>I: 0.15</td>
<td>C: 0.34</td>
</tr>
<tr>
<td></td>
<td>International Physical Activity Questionnaire (IPAQ)(^a)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>778.50 (694.58)</td>
<td>1005.91 (800.02)</td>
<td>G: 0.00</td>
<td>0.2</td>
<td>Tx: 0.66</td>
</tr>
<tr>
<td>Post</td>
<td>1331.42 (990.12)</td>
<td>1179.73 (991.558)</td>
<td>T: 6.13*</td>
<td>I: 1.47</td>
<td>C: 0.24</td>
</tr>
<tr>
<td></td>
<td>Quality of Life Inventory (IPAQ)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>-0.50 (1.72)</td>
<td>-0.25 (1.54)</td>
<td>G: 0.12</td>
<td>0.04</td>
<td>Tx: 0.36</td>
</tr>
<tr>
<td>Post</td>
<td>0.16 (1.99)</td>
<td>0.23 (1.47)</td>
<td>T: 11.48***</td>
<td>I: 0.27</td>
<td>C: 0.32</td>
</tr>
</tbody>
</table>

Note: G = Group effect; T = Time effect; I = Interaction effect; Tx = Treatment group; C = Control group; *** p < .001; ** p < .01; * p < .05; \(^a\) n=46 due to incomprehensible data; \(^b\) n=47 due to missing data

**Participants’ evaluation**

A survey concerning the opinions of the treatment program was given to the treatment group at the end of the study. Because of a technological problem only 14 participants completed all questions (58%). Five (36%) respondents who answered the survey did not complete all modules in the treatment program.

As presented in Table 3, most of the participants who answered the survey were pleased or more than pleased with the treatment program (64%).
### Table 3. Participants’ evaluation of the treatment program (n = 14)

<table>
<thead>
<tr>
<th>Overall, how satisfied do you feel with the treatment?</th>
<th>How would you judge the importance of the correspondence with your internet therapist?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very satisfied</td>
<td>Non-existent 1 (7.1%)</td>
</tr>
<tr>
<td>Mostly satisfied</td>
<td>Not important 4 (28.6%)</td>
</tr>
<tr>
<td>Neutral</td>
<td>Somewhat important 3 (21.4%)</td>
</tr>
<tr>
<td>Somewhat dissatisfied</td>
<td>Important 4 (28.6%)</td>
</tr>
<tr>
<td>Very dissatisfied</td>
<td>Very important 2 (14.3%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How would you judge the quality of the treatment modules?</th>
<th>How did you experience the home assignments in the treatment program?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good</td>
<td>Just enough 8 (57.1%)</td>
</tr>
<tr>
<td>Satisfactory</td>
<td>Too many 3 (21.4%)</td>
</tr>
<tr>
<td>Unsatisfactory</td>
<td>Too few 3 (21.4%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How would you judge the readability of the treatment modules?</th>
<th>To what extent do you consider that you followed the program?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate</td>
<td>In every detail 1 (7.1%)</td>
</tr>
<tr>
<td>Easy</td>
<td>For the most part 8 (57.1%)</td>
</tr>
<tr>
<td>Too easy</td>
<td>Moderately 1 (7.1%)</td>
</tr>
<tr>
<td></td>
<td>Not so much 2 (14.3%)</td>
</tr>
<tr>
<td></td>
<td>Not at all 2 (14.3%)</td>
</tr>
</tbody>
</table>

### Discussion

The aim of this study was to develop and evaluate a treatment program for mild to moderate MDD based on physical activity administered via the Internet. The hypotheses were reduced levels of depressive and anxiety symptoms and at the same time increased levels of physical activity and quality of life for participants in the treatment condition as compared to the control. In addition, a correlation was expected between reductions in depressive symptoms and increased levels of physical activity for all subjects.

Results showed a statistically significant interaction effect, favouring the treatment condition compared to the control, with a moderate between groups effect size of Cohen’s $d = 0.61$ and $d = 0.68$ on self-report measures of depression, MADRS-S and BDI-II. Within group effect sizes for these measures were large with Cohen’s $d = 0.88$ and $d = 1.39$ respectively. These results support our first hypothesis.

The effects found in the current study are in line with efficacy outcomes from other well-established evidence based treatments. For example, Mead et al (2009) examined physical activity for depression and found a between groups effect size of $d = 0.42$ for high quality studies, and $d = 0.82$ for all included studies in the analysis. In addition to this, Andersson and Cuijpers (2009) found a
between group effect size of supported Internet- delivered CBT treatments of $d = 0.61$.

However, results in this study showed no significant difference between the groups on secondary measures of anxiety, physical activity and quality of life (BAI, IPAQ and QOLI). In addition to this, no significant correlation between increased levels of physical activity and decreased depressive symptoms was found. These results do not support the remaining four hypotheses.

One possible reason for the lack of significant results on the secondary measures is the general regression to the mean effect and possible spontaneous remission in the control group. Within-groups effect sizes on all secondary measures in the control group were between Cohen’s $d = 0.24$ and $d = 0.79$ and significant time effects were found on all measures. This can be due to factors such as positive climatic changes during springtime, Hawthorne effects from being a part of the study and placebo effects.

Another explanation could be the weekly monitoring on changes in depressive symptoms where participants in the control group answered the MADRS-S. Feedback on weekly-administered questionnaires has been proven to reduce depressive symptoms in psychiatric outpatients (Newnham, Hooke & Page, 2010).

A third explanation for the non-significant result on the secondary measures could be the low statistical power of the study due to a small sample size of $N = 48$. Calculations made prior to the study indicated that a sample size of $N = 80$ would be required to find significant interaction effects if they exist. The main reason for the small sample size was in part the limited amount of participants registering their interest in the study ($N = 159$) and in part the large percentage of excluded participants (69.8%). The main reason for this exclusion rate was high self-rated levels of physical activity for participants registered for the study.

Finally, in line with the results in this study, a similar trial found no relation between reduced depressive symptoms and secondary measures such as changes in quality of life (Andersson et al., 2005).

The most surprising findings were the non-significant interaction effect on IPAQ and the non-significant correlation between IPAQ and measures on depression. Two explanations for these results should be considered.

Firstly, a large amount of the participants in the study showed moderate or high levels of physical activity at pre-treatment (60.5%). This ceiling effect in the sample provided small opportunities for increased levels of physical activity.
Ideally, only people with a low level of physical activity should have been included in the study since those individuals were expected to gain most from the treatment. However, such a rigorous exclusion would have left few participants to the study.

Secondly, the IPAQ has several issues in need of consideration. Ekelund et al. (2006) found that people significantly overestimate their physical activity using the IPAQ compared to an objective measure. This brings some uncertainty to the results found in this study. It is possible that people in the treatment condition overestimated their physical activity less at post-treatment, than people in the control condition, since the treatment included detailed monitoring of physical activity. Also, data cleaning was needed due to unreasonable answers. This was done to answers from eight participants according to principles from International Physical Activity Questionnaire (2005). This process may have led to misinterpretations of the intended answers of the respondents. Lastly, four participants gave incomprehensible answers to questions in the IPAQ, indicating misunderstandings of the instructions. Imputation of data using last observation carried forward, was used for two of them.

In summary, the findings in this study indicate that the treatment evaluated is effective for depressive symptoms for people with MDD, but there is no evidence of effectiveness in raising levels of physical activity. Since the effects found on depressive symptoms cannot be explained by changes in physical activity, questions are raised concerning the active ingredients in the treatment.

Some experts state that there is no dose-response relationship between levels of physical activity and depressive symptoms (Kesaniemi et al., 2001). This implies that other aspects than the frequency, duration and intensity of physical activity mediates changes in depressive symptoms. Considering this, it seems unlikely that improved fitness and related physiological changes account for reduced depressive symptoms in this study. Rather, it seems that other aspects of the treatment accounts for the obtained effects.

Firstly, earlier research has shown that self-help programs in which support is provided are more effective than programs without support (Andersson, 2006; Andersson & Cuijpers, 2009). In this program, feedback based on MI principles was given each week. This could possibly explain the positive outcome to some extent.

Secondly, the program included features of behavioural activation strategies such as activity planning and monitoring. This was introduced early in the program and continued until the end (see Appendix I). Research shows that behavioural activation is an effective treatment for depression (Jacobson,
Martell & Dimidjian, 2001), and this aspect of the program could account for some of the positive outcome effect on depressive symptoms.

Thirdly, a reoccurring feature of the treatment was autonomous goal setting. Participants were encouraged to set efficient goals every week using the SMART principle (Hassmén & Hassmén, 2005) and to achieve them. Studies have shown increased levels of self-efficacy in people striving for and achieving their goals (Biddle & Fox, 1998; Perri, McAdoo, Lauer, McAllister & Yanzey, 1986). To obtain goals and to enhance self-efficacy for physical activity can be seen as positively reinforced behaviour. According to the spiral model, based on the same principles as behavioural activation, this can be a way to break depressive patterns and inactivity (Haase et al., 2010).

Other fundamental ingredients in the treatment were self-determination theory, stages of change theory and acceptance and mindfulness strategies. A pedometer was also sent to each participant in the treatment condition. The purpose of these interventions was to increase adherence to the program and to maximize the likelihood of participants engaging in physical activity, but could also have some effects on depressive symptoms.

58 % of the participants in the treatment condition completed all nine text modules (Fig 1). This adherence rate is a cause of concern but are in line with earlier studies of Internet based treatments showing just over half of the participants completing all sessions (Waller & Gilbody, 2009).

All participants included in the study completed post-testing, which is uncommon for studies of this kind. Usually, the last observation carried forward principle is used for missing data. Having a complete dataset for both pre- and post-testing for both conditions increases reliability and validity of the results. However, imputation of data was used for four participants who started other treatment (pharmacotherapy or psychotherapy) or made changes in their medication during the study. Since it is feasible that other active treatments influence outcome measures in this study, a conservative way of handling data was preferred.

Regarding the evaluation of the treatment program, most participants were pleased or more than pleased with the treatment overall (64%). Because of a technical problem, only 14 (58.3%) respondents in the treatment condition gave complete answers. Five of these did not complete the program. This low level of participation in the evaluation may have affected the general assessment of the program.
There were significantly more females than males in the sample. This is common for studies on depression but should be considered as a limitation for the generalizability of the results. In addition, the mean age in the sample was high (table 1) with only 10 participants under 40 years of age.

Other limitations of this study were the small sample resulting in a low statistical power, the lack of objective measures of physical activity, the high level of physical activity in participants at pre-treatment and the lack of measures on mediating factors such as self-efficacy, motivation and therapist support. This makes conclusions on how the treatment program was effective hard to make.

Future research should dismantle the different parts of the treatment, such as physical activity, therapist support and self-efficacy, to estimate to which extent they influence the outcome. Studies should include objective measures of physical activity as well as measures of mediating factors to distinguish between active ingredients of the treatment.

This study has introduced a new potentially effective internet-based treatment for depression based on a physical activity intervention. The treatment program may be a valid alternative to traditional treatments for depression for people unwilling to use antidepressant medication or psychotherapy. It may also be a first step in developing an intervention supporting people wishing to increase their level of physical activity. This has implications for other health related issues on a national level. For example, the program could become a supplement for prescriptions on physical activity made by health professionals (Professional Compound for Physical Activity [Yrkesföreningar för fysisk aktivitet], 2008). Because of the internet-delivered nature of the program, it may be considered cost-effective (Titov et al, 2009) and is not limited by large geographical distances.

References


Appendix I: The treatment program

Module 1

- Brief introduction to depression: signs and symptoms.
- Explanation of depression using the spiral model.
- Overview of different types of physical activation (PA), and how PA can be helpful to treat depression.
- Presentation of treatment structure and how to use the KHS.
- Presentation of how to set up and use the pedometer that was given the subjects along with module 1.
- Home assignments:
  - Participants are asked to give a brief narrative of their depressive symptoms and prior experience of PA.
  - What are the participants thoughts about their chance of increasing the level of PA?
  - Which are the participants main barriers for PA?
  - The participants are asked to use the pedometer in three walks during the coming week and to register the total number of steps taken.

Module 2

- Introduction on how a sedentary lifestyle influences overall health.
- Description of how PA affects the human body in physical, mental and neurological ways and level of PA needed to acquire positive health effects.
- Presentation of stages of change.
- Most common barriers for PA and how to overcome them.
- Examination of pros and cons of increasing PA or maintaining the status quo, using a motivational balance exercise.
- Home assignments:
  - What are the participants thoughts on the treatment program so far?
  - Which stage of change do the participants find themselves in?
  - What do the participants believe is their main obstacle for PA?
  - Motivational balance exercise
  - Subjects are encouraged to keep taking three walks the coming week and if they want, to increase the length of the walks.
Module 3

• Introduction to goal setting using SMART goal setting principles
• How to work with activity scheduling to incorporate regular PA into everyday life.
• Examples of different forms of PA
• Important aspects of change management and how to increase self-efficacy for PA.
• Home assignment:
  o SMART goal-setting for the next week.
  o Making a schedule of PA activities to meet the goals for next week.
  o Patients are encouraged to register all PA conducted, including walks (using the pedometer), during the week.

Module 4

• Introduction on how to follow up and review the goal and schedule from last week.
• Possible links between PA and mood.
• Home assignment:
  o From this week on, SMART goal-setting, activity scheduling and registration of PA for the coming week are incorporated as a weekly routine.
  o Participants are asked to review the goal and the schedule from the past week.
  o Which were the biggest obstacles? How did the participants deal with them?

Module 5

• Introduction to handling setbacks and relapses during behaviour change
• Presentation of the most common thinking errors when afflicted by setbacks and how to deal with them.
• How to reward progress in PA and to facilitate long lasting behaviour change.
• Home assignments:
  o Do the participants recognize any of the common thinking errors when afflicted by setbacks?
  o What progress have the participants experienced so far? How can these accomplishments be rewarded?
Module 6

- How to get sufficient rest and recovery after PA
- General nutrition advice before and after PA.
- Home assignments
  - What do the participants find particularly important as a “take home message” regarding rest and nutrition?

Module 7

- Participants are introduced to aspects of acceptance and commitment theory, and are initiated to think about how PA can be part of heightened quality of life.
- Subjects learns about living in accordance with what they value in terms of health and PA, and are introduced to the concept of having a permissive attitude towards all experiences when moving in their valued direction, even the difficult ones.
- Home assignment:
  - Valued direction exercise focusing on health and PA.

Module 8

- Mindfulness walking and how to incorporate acceptance in the struggle to increase and maintain PA.
- Home assignments
  - Participants are encouraged to do a mindfulness walking exercise. What were their experiences?

Module 9

- How to maintain PA after the end of the treatment program.
- Summary of the previous modules.
- Home assignment:
  - Participants are encouraged to answer the post-treatment questionnaires administered over the Internet.