The effectiveness of RUNNING THERAPY on the symptoms of individuals with anxiety and/or depressive disorder

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PREFACE

This thesis was the final work of my Master Public Health and Society, Faculty of Social Science, Wageningen University, the Netherlands. It served as documentation of my work during the study, which has been made from winter 2008 until autumn 2009. The principal of this study was physiotherapy practice "Fysiotherapie & Sport van Woerkom" and Wageningen University.

The study presented in this thesis was primarily concerned with the effectiveness of Running Therapy (RT) for individuals with anxiety and/or depressive disorders. Moreover, it provided information about the rationales of individuals to choose for RT. A pure passion for running and a great interest in mental health were my rationales to choose RT as subject for my Master thesis.

I would like to express my gratitude to my supervisors Hilde Tobi and Lenneke Vaandrager. This thesis would never have become a reality without their encouragement, advice and unique support. It was to them I owe by biggest "thank you" for letting nothing be unquestioned.

Furthermore, I would like to thank Simon van Woerkom, who contributed to the completion of this thesis, supported me along the way and let me become a running therapist. In addition, I would like to thank Bram Bakker for his cooperation. Moreover, I would like to thank Willeke Joosten, Roland Luykx and Björn van Rees for participating as running therapists in the RT intervention.

Finally, I wish to express my greatest thanks to my wonderful family and friends, who have supported me and especially Laurien for her patience and understanding.

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ABSTRACT

BACKGROUND: Despite the observed reductions in anxious and depressive symptoms in numerous exercise intervention studies, the effectiveness of Running Therapy (RT) was not yet convincingly proved. Therefore, a more systematic research on the application and therapeutic potential of RT to mental health needed to be done. Moreover, individuals' rationales to choose for RT needed to be studied in order to gain detailed information about participants' thoughts, feelings and experiences about RT. This might lead to the recognition of rationales that, up to this point, were neither considered nor expected.

OBJECTIVE*:* To examine the effectiveness of RT on the symptoms of individuals with anxiety and/or depressive disorders and to provide information about the rationales of individuals to choose for RT.

SETTING: A RT intervention was conducted to examine the effectiveness of RT. In total 24 training sessions were completed during this intervention: two group training sessions under supervision of one or two running therapists and one individual training session per week for a period of eight weeks OR one group training session under supervision and one individual training session per week for a period of twelve weeks. Each training session consisted of a warm-up and cooling-down and was scheduled to last 60 to 90 minutes. The intensity of the training sessions was low to moderate, which conformed to the aerobic heart rate zone. Participants of the intervention and the semi-structured interviews were recruited from: two physiotherapy practices, one Mental Health Care Institution and one psychologists practice. All were located in the provinces Gelderland and Brabant, the Netherlands.

METHODS: Quantitative study: participants of the RT intervention (n=8) completed the Symptom Checklist-90-Revised (SCL-90-R) before and after the intervention. Qualitative study: semi-structured interviews were held with interviewees (n=11) to examine the rationales of individuals to choose for RT.

RESULTS: On average the standardized SCL-90-R anxiety and depression scores had decreased statistically significant after RT treatment. However, this improvement was not clinically significant: on average, the improvements were not big enough to result in a better category compared to the general population. Results of the semi-structured interviews seemed to confirm the importance of RT as alternative treatment for mild to moderate and severe depressive and/or anxiety disorders, since several participants who used psychotropic medication and who quitted – due to the perceived negative side effects – chose for RT. Furthermore, participants' rationales seemed to emphasize the importance of the proactive health professional-patient relationship, which was essential to ensure adherence to RT. Moreover, the social environment nourished and encouraged participants' initiation and continuation in RT.

CONCLUSIONS: Although improvements were achieved after eight or twelve weeks of RT treatment, the absence of a control group did not allow the conclusion that RT was responsible for producing reductions in anxiety and depressive symptoms. Moreover, study results seemed to underline the importance that: participants of RT were ready to change their physical activity behavior; RT was delivered in a group and ongoing social support before, during and after the RT was made available.

KEY WORDS: Running Therapy, anxiety & depressive disorders, SCL-90-R, participation rationales.

1 INTRODUCTION AND CONTEXT

There is little systematic research on the effectiveness of Running Therapy (RT) on mental health and on its therapeutic potential. Moreover, literature on individuals' rationales to choose for RT is severely limited. This study examined the effectiveness of RT on the symptoms of individuals with anxiety and/or depressive disorders and the rationales of individuals to choose for RT.

Anxiety and mood disorders are major public health problems with high socio-economic costs in the society. Although it is difficult to give an estimate of the prevalence of anxiety and mood disorders, since most mental disorders are associated with one another, research findings revealed that anxiety has the highest prevalence (12-month prevalence median: 12%: 36.3 million subjects affected) among the mental disorders, followed by mood disorders (7.8%: 20.8 million subjects affected) in the general EU population (Wittchen and Jacobi, 2005). The World Health Organization (WHO) stated in 1990 that depressive disorder was the fourth leading cause of disease burden in terms of disability. The disability caused by depressive disorder resulted in more days in bed due to illness, more work days lost, increased impairment at work, and a high use of health services, which all led to high socio-economic costs. Moreover, the comorbidity of anxiety with depressive disorder further increased the disability as experienced by sufferers (Lecrubier, 2001).

A range of pharmacological and psychosocial interventions for preventing, treating and managing anxiety and/or depressive disorders have been studied in order to tackle the burden of these mental disorders. One of the recently investigated interventions was exercise intervention, which can be characterized in terms of: frequency of exercise per week, duration, intensity, type (aerobic versus anaerobic), and total energy expenditure (Stathopoulou et al., 2006).

Exercise implies a regular, structured, leisure-time pursuit and can be divided into aerobic (training of cardiorespiratory or aerobic endurance) and anaerobic, also called nonaerobic or resistance exercise (muscular strength, flexibility, coordination, and relaxation). Aerobic exercise, such as running, can be defined as "any activity that uses large muscle groups, can be maintained continuously, and is rhythmic in nature" (The American College of Sports Medicine, 2005). It involves exertion, which increases the flow of blood through the heart. The term "aerobic" means "with oxygen" and refers to working at a level where the large muscles get adequate oxygen from the blood to sustain prolonged physical activity. The opposite form of aerobic exercise is anaerobic exercise. "Anaerobic" means "without oxygen" and refers to the initial phase of exercise or any short burst of intense exertion, such as weight lifting, in which the glycogen or sugar is consumed without oxygen.

Most exercise interventions have used the aerobic form of exercise, with running as the most common activity, in order to obtain evidence to prevent, treat or manage anxiety and/or depressive disorders. Only a few studies discussed about "exercise therapy" (e.g. Tkachuk and Martin, 1999) or "Running Therapy" (e.g. Bosscher, 1993). A few studies have compared the effects of aerobic exercise to the effects of anaerobic exercise for the treatment of depressive disorder (e.g. Krogh et al., 2007) and have shown that anaerobic exercise may be equally effective in reducing depressive symptoms compared to aerobic activity (Stathopoulou et al., 2006).

The potential use of aerobic exercise as an alternative or complementary treatment for depressive disorder has received attention, partly because of its advantages over psychotropic medication, which was the most frequently used treatment for depression (Robinson et al., 2005) and anxiety (Culpepper et al., 2007). Psychotropic medication has serious side effects, which can impair patients' quality of life and reduce compliance (Babyak et al., 2000). This, in contrast of the effect of moderate, prolonged aerobic exercise on physical and mental health status, which is generally quite positive with only a few side-effects (Dudgeon et al., 1998).

There is a substantial body of evidence indicating a positive association between regular physical exercise and the severity of anxiety (Otto et al., 2007; Salmon, 2001) and depressive symptoms (Dunn et al., 2005; Strawbridge et al., 2002; Biddle et al., 2000). Regular physical exercise can not only diminish symptoms, but also can have a great potential in preventing the development of anxiety and depressive disorder. Several studies have shown that patients with stress-related mood disorders, who engage in physical exercise alone (Babyak et al., 2000; Martinsen, 1990a, 1990b) or in combination with taking psychotropic medication (Blumenthal et al., 1999), have shown clinical improvements and ranked exercise as the most important aspect of the therapy. The above mentioned studies concluded that physical exercise can reduce anxiety and depressive symptoms, despite their methodological differences with respect to: 1) inclusion criteria with regard to measurement of anxiety or depressive disorder (self-reported symptoms or clinical diagnosis), 2) sample characteristics (healthy participants or clinical population) and 3) research design (differences in control groups, randomization, periods of training and follow-up and type of exercise).

According to a population-based longitudinal twin study (1991-2002) by de Moor et al. (2008), the positive association between regular physical exercise and the severity of anxiety and depressive symptoms was not because of causal effects of exercise. De Moor et al. falsified the causal hypothesis by taking genetic variation among individuals, a potential confounding factor, into account. The study of de Moor et al. has shown that twins, who exercised more, did not display fewer anxious and depressive symptoms than the genetically identical co-twins who exercised less. Other studies as well have examined the role of genetic variation and ascribed the variation in anxious and depressive symptoms to heritable traits, with genetic factors explaining about 40 to 50 per cent of the variation (Boomsma et al., 2000) and exercise behavior about 50 to 60 per cent (Stubbe et al., 2006).

The methodological differences in exercise interventions have questioned the effectiveness of either aerobic or anaerobic exercise on the symptoms of anxiety and/or depressive disorder. Despite the observed reductions in anxious and depressive symptoms in a number of studies, it can be concluded that the effectiveness of exercise, in particularly RT, is "plausible, but not yet convincingly proven" (Multidisciplinaire Richtlijnontwikkeling Depressie, 2005: page 113). Therefore, more systematic research on the application and therapeutic potential of RT to mental health, especially to anxiety and/or depressive disorders, needed to be done.

1.1 Research objective

The purpose of this study was two-fold: to examine the effectiveness of RT on the symptoms of individuals with anxiety and/or depressive disorders and to provide information about the rationales of individuals to choose for RT.

1.2 Research questions

The general research question of this quantitative study was:

WHAT IS THE EFFECT OF RUNNING THERAPY ON THE SYMPTOMS OF INDIVIDUALS WITH ANXIETY AND/OR DEPRESSIVE DISORDER?

The elaboration of the subjoined specific research questions served to better understand the concept of RT:

- What is Running Therapy?
- What is the dose-effect relationship between aerobic exercise and depressive symptoms?
- What are the psychological, cognitive and physiological effects of aerobic exercise?
- What is the role and characteristics of the running therapist?
- What is the resistance and barriers among patients to exercise?
- What is the resistance and barriers among health care professionals to exercise?
- What are the symptoms of anxiety and depressive disorders?

To provide information about the rationales of individuals to choose for RT, the subjoined research question was conducted:

WHAT ARE THE RATIONALES FOR INDIVIDUALS TO CHOOSE FOR RUNNING THERAPY?

1.3 Outline of the thesis

The study presented in this thesis was primarily concerned with the effectiveness of RT on the symptoms of individuals with anxiety and/or depressive disorders. The literature study was elaborated in chapter two. Chapter three contained the used methods in this study. It further elaborated on the setting (3.1), the way in which the RT intervention was conducted and which measurement was used to examine the effect of RT on the symptoms of individuals with anxiety and/or depressive symptoms (3.2). How the data of the research question: *"What are the rationales for individuals to choose for Running Therapy?"* were collected, was elaborated in paragraph 3.3. The results and conclusions of this study can be found in chapter four. The discussion was elaborated in chapter five. The thesis finished with the reference list and appendices.

2 LITERATURE REVIEW

2.1 Method: Effect of Running Therapy

The literature study addressed the following specific research questions:

- What is Running Therapy?
- What is the dose-effect relationship between aerobic exercise and depressive symptoms?
- What are the psychological, cognitive and physiological effects of aerobic exercise?
- What is the role and characteristics of the running therapist?
- What is the resistance and barriers among patients to exercise?
- What is the resistance and barriers among health care professionals to exercise?
- What are the symptoms of anxiety and depressive disorders?

The Wageningen UR Digital Library was used to find scientific literature, especially on the subject of exercise interventions. The following keywords in the database Scopus and Web of Science were used: "Depression" OR "depressive disorder" OR "mood disorder" OR "anxiety" OR "anxiety disorder" AND "exercise" OR "exercise therapy" OR "physical exercise" OR "aerobic exercise" OR "running therapy" OR "burden" OR "Symptom Checklist-90-Revised". The articles published between 1980 and 2009 were selected considering their relevance for this study. The selected articles were also used as resource for related scientific articles. The same keywords were used in PubMed and Google Scholar.

2.2 Results: Effect of Running Therapy

2.2.1 Running Therapy

Exercise has been described as "therapeutic" and used as type of therapy in its own right since the late seventies and early eighties. The advantages of both aerobic and anaerobic forms of exercise on mental health have been studied, and running has been used as the most common activity in exercise interventions for both historical and practical reasons. This possibly resulted in "adding semantic confusion to a field already lacking experimental precision by using the terms "exercise therapy" and "Running Therapy" interchangeably" (Hays, 1994: page 726).

Bosscher can be seen as the pioneer of RT in the Netherlands, since he was the first who examined the effect of RT in depressed patients in 1991. He defined it as *"het aanleren van de vaardigheid om drie à vijf keer per week minimaal een half uur ontspannen te kunnen hardlopen"* (Bosscher, 1991: page 105). Psychiatrist Bram Bakker and physiotherapist and running therapist Simon van Woerkom – authors of the first Dutch guideline for runners and professionals with regard to RT – defined it as *"het therapeutisch inzetten van de "rustige duurloop" ten behoeve van mensen met een depressie of andere psychische klachten"* (Bakker and van Woerkom, 2008: page: 18). Both definitions specified RT in terms of activity dose, which can be interpreted as the frequency, duration or intensity of the running activity (Haskell et al., 2007).

2.2.2 Dose-effect relationship

According to the definitions of RT, patients need low to moderate intensity of endurance running for a minimum of 30 minutes for three days a week. This activity dose almost conforms to the public health recommendation for physical activity, which was established in order to promote and maintain health. It advises all adults “to engage in 30 minutes or more of moderate intensity physical activity on most and preferably all days of the week to reduce the risk of early death and morbidity from a variety of diseases, such as cardiovascular disease”. The public health recommendation emphasizes the benefits of physical activity mainly on the physical aspects of health by speaking in terms of “diseases” (and not “disorders”), while benefits on the mental aspect of health can be reached simultaneously (e.g. Salmon, 2001).

Recently several studies have examined the dose-effect relationship between aerobic exercise and depressive symptoms. A study done by Dunn et al. (2005) showed that aerobic exercise with an energy expenditure of 17.5-kcal/kg/week – which is consistent with the public health recommendation of 30 minutes of moderate aerobic exercise for five days a week – was an effective treatment for major depressive disorder (MDD) of mild to moderate severity, whereas a lower dose was comparable to a placebo effect. No difference in the reduction and remission of depressive symptoms was found regarding the frequency of three or five times per week of aerobic exercising when a 17.5-kcal/kg/week dose was used. This might explain the frequency of three times running per week for a minimum of 30 minutes in the RT definition. Furthermore, a study done by Singh et al. (2005) showed that high progressive resistance training (PRT) was more effective than low intensity PRT or general practitioner care for the treatment of older depressed patients. This partly explained the low to moderate intensity of the endurance running in the definition. Moreover, a study done by Blumenthal et al. (2007) showed that there was no difference in the severity of depressive symptoms between exercising alone or in a group.

2.2.3 Mechanisms: psychological, cognitive and psychophysical

Running has been reported to induce not only psychological, but also cognitive and physiological effects. A randomized controlled trial by Foley et al. (2008) has demonstrated that aerobic exercise was associated with positive psychological and cognitive changes in those with depressive disorder. Foley et al. have shown that change in depression severity was significantly inversely associated with change in coping efficacy and change in episodic memory, which are inter-related cognitive and physiological variables. Coping efficacy relates to the confidence a person has that s/he can perform a task despite challenges to doing so. It is a sub-construct of self-efficacy that has been identified to improve with exercise and may relate to depression remission (Bandura, 1997 in Foley, 2008). According to a study by Boecker et al. (2008), exercise may also have several psychophysical effects, such as stress reduction, reduced pain perception and a state of euphoria while running, which can be referred as “runner's high” where feelings like "pleasantness", "inner harmony", or "boundless energy" can occur. Boecker et al. have shown that the level of euphoria significantly increased after running. These findings supported the "opioid theory" of the runner's high and suggested region-specific effects in frontolimbic brain areas that were involved in the processing of affective states and mood. Taken the findings of the above mentioned studies together, it can be justified that several synergistically interacting changes were occurring during exercise, in particularly running, that might explain its benefits as treatment for individuals with depressive disorder. These changes were less well investigated for individuals with anxiety disorder.

2.2.4 The role and characteristics of the running therapist

The role of the running therapist is to give support and prevent exhaustion and pain during the RT sessions. S/he emphasizes the health benefits of regular running participation, recognizes the potential for competition between the therapist and the patient (Hays, 1994) and small incremental increases in order to build self-efficacy. S/he also provides individualized attention and tailored goal setting to change behavior among the patient, since they need personal acknowledgment of their efforts, and oversight of their progress. Moreover, the therapist instills confidence in patients' ability to recover their wellness and develop resiliency (Richardson et al., 2005).

A running therapist should have a sufficient physical condition to run and should be creative, enthusiastic, supportive, energetic, patient, open-minded and grounded in knowledge and skills of psychology and/or the physiological aspect of sport science (Richardson et al., 2005; Hays, 1994). S/he should, just like the patient, not have somatic contra-indications to running (e.g. cardiovascular diseases) or overuse it (Hays, 1994). Furthermore, the running therapist should be conscious of the limits of one's skills and competence, and the factors training, coaching, and compliance, which might offer a variety of pitfalls and mixed role relationships. Moreover, the running therapist should be aware of the Ethical Principles and Standards of the Association for Applied Sport Psychology's (AASP).

2.2.5 Resistance and barriers among patients

A number of studies have examined resistance and barriers to exercise among patients and health care providers, but none of them specified to RT. This should be taken into account when discussing about this subject.

As mentioned earlier, research findings have shown that regular moderate exercise, such as running, might be beneficial for anxiety and depressive symptoms. Despite these health benefits, resistance and barriers among patients could have the upper hand. The first barrier of the patient could contain around the initiation of the exercise. Regarding the role of the mental health professionals, most of the patients expect they will talk about their psychological problem, receive expert help and support, and might receive a suggestion, and possibly a prescription, for psychotropic medication. They do not expect their mental health professional to suggest, implement and maintain an exercise intervention, which can result in anger and resistance among the patient (Pollack, 2001). Another barrier could be that depressed patients are often unmotivated, de-energized and apathetic and characterized by a low self-worth, self-confidence, and self-efficacy and encounter difficulties in decision-making and problem-solving (Seime, 2007; Ussher et al., 2007; Richardson et al., 2005), which make it difficult to start and maintain the exercise intervention. These barriers might explain the low compliance of exercise recommendations in comparison with psychotropic medication (Ussher et al., 2007; Wing et al., 2002; Pollack, 2001). Furthermore, the difficulty to make healthy lifestyle changes (Pollack, 2001) and the absence of the "no-pain, no-gain" philosophy among persons with mental disorders – which can be used to encourage them to continue exercise participation (Richardson et al., 2005) – make it even more difficult to start and maintain the exercise intervention. Moreover, the way and the number of RT sessions that are covered by health insurances can possibly be a barrier for patients to start and maintain this form of exercise.

2.2.6 Resistance and barriers among health care professionals

According to a study done by Pollack (2001), health care providers can have resistance to employ exercise and maintenance as part of their treatments. The following reasons can be mentioned for their resistance:

- Exercise promotion and maintenance is not included in training of most health care professionals;
- There is no widely belief among mental health professionals that increasing and maintaining exercise can play a critical and causal role in the reduction in depressive symptoms;
- An activist approach to exercise may be experienced by the majority of psychotherapists as theoretically and methodologically inconsistent with their treatment approaches;
- Getting patients to make healthy lifestyle changes is extremely difficult considering educational, psychological and social barriers, co-morbid conditions and poor timing (Feinstein et al., 1999).

Furthermore, employing exercise requires an understanding of the biopsychosocial domains, as well as a significant amount of time and effort from the therapist. Other barriers that can be mentioned are patients' feelings of transference and therapists' feelings in the therapy and/or towards the patient. Moreover, patients could experience their exercise relapse as failure accompanied by feelings of shame, possibly resulting in anger towards the therapist (Pollack, 2001).

2.2.7 Symptoms of generalized anxiety and depressive disorders

Table one depicted the symptoms of the generalized anxiety disorder, major depressive disorder and depressive disorder not otherwise specified. A description of these symptoms is considered relevant when examining the effect of RT on the symptoms of individuals with anxiety and/or depressive disorders.

Table 1: Characteristics and symptoms of several mood disorders according to the 4th edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM) (American Psychiatric Association, 2000).

MOOD DISORDERS	SYMPTOMS
Generalized Anxiety Disorder is characterized by at least six months of persistent and excessive anxiety and worry. These symptoms are present with three or more of the six symptoms	1. Restlessness or feeling keyed up or on edge 2. Being easily fatigued. 3. Difficulty concentrating or mind going blank 4. Irritability 5. Muscle tension 6. Sleep disturbance
Major Depressive Disorder (MDD) is characterized by one or more Major Depressive Episodes (i.e., at least two weeks of depressed mood or loss of interest in combination with at least four additional symptoms of depression)	1. Depressed mood most of the day, nearly every day, as indicated by either subjective report or observation made by others 2. Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day 3. Significant weight loss when not dieting or weight gain or decrease or increase in appetite nearly every day 4. Insomnia or hypersomnia nearly every day 5. Psychomotor agitation or retardation nearly every day 6. Fatigue or loss of energy nearly every day 7. Feelings or worthlessness or excessive or inappropriate guilt nearly everyday 8. Diminished ability to think or concentrate, or indecisiveness, nearly every day 9. Recurrent thought of death, recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide
Depressive Disorder Not Otherwise Specified is included for coding disorders with depressive features that do not meet criteria for MDD, Dysthymic Disorder, Adjustment Disorder With Depressed Mood, or Adjustment Disorder With Mixed Anxiety and Depressed Mood	The symptoms of Depressive Disorder Not Otherwise Specified correspond with depressive symptoms, but often with fewer items required for depressive disorders, such as MDD, Dysthymic Disorder, or Adjustment Disorder With Depressed Mood, or Adjustment Disorder With Mixed Anxiety and Depressed Mood

3 METHODS

The methodology used in this study included desk research to collect secondary data and field work to collect primary data. First, the setting in which participants of the RT intervention and the semi-structured interviews were recruited was elaborated (3.1). Subsequently, the method used for the RT intervention (3.2) and the semi-structured interviews (3.3) were elaborated.

3.1 Setting

A convenience sampling strategy was used to recruit participants for the RT intervention from: two Health Centers, one Mental Health Care Institution and one psychologists practice. A convenience sampling strategy was also used to recruit participants for the semi-structured interviews from Health Center "De Kroonsteen". All settings are located in the provinces Gelderland and Brabant, the Netherlands.

3.1.1 Health Centers: De Kroonsteen (Malden) and De Roerdomp (Nieuwegein)

"Fysiotherapie & Sport van Woerkom" is a physiotherapy practice, which is part of Health Centre "De Kroonsteen" in Malden. RT was offered by the researcher and running therapist Carmen Voogt in cooperation with physiotherapist and running therapist Simon van Woerkom, who is the instigator, author and instructor of the Dutch post HBO course "Running Therapy". (For a reflection of the researcher as running therapist during the RT intervention, see appendix one). Participants of the RT intervention were also recruited from Health Centre "De Roerdomp" in Nieuwegein, where RT was offered by physiotherapist and running therapist Roland Luykx.

3.1.2 Mental Health Care Institution: De Gelderse Roos (Arnhem)

"De Gelderse Roos" is a Mental Health Care Institution, which was established in 1996 by a merger of the organizations: RIAGG Arnhem, RIAGG Rivierenland, General Psychiatric Hospital Wolfheze, Rehabilitation Centre Human and Society and Association Veluweland. "De Gelderse Roos" provides ambulatory and clinical care for people with psychological and psychiatric disorders. The selected Mental Health Centre Institution was located in Arnhem. RT was offered by physiotherapist and running therapist Björn van Rees.

3.1.3 Psychologists practice: De Psychologenpraktijk (Breda)

"De Psychologenpraktijk" is an independent psychologists practice, established in 2005 by Xandra Bakker, Els van den Heuvel and Willeke Joosten. RT was offered by health psychologist and running therapist Willeke Joosten.

3.2 Quantitative study: Running Therapy intervention

To examine the question: *"What is the effect of Running Therapy on the symptoms of individuals with anxiety and/or depressive disorders*?" a RT intervention was conducted.

3.2.1 Study design

A one-group pre-test-post-test study design was used, which contained individuals, that from the different settings were regarded as one group, pre-tested, exposed to the intervention and post-tested (O_1 X O_2). Score data (anxiety and/or depressive symptoms) were collected before and after the RT intervention. Due to pre-testing and post-testing, the effect of RT was measured.

3.2.2 Research hypothesis

A reduction in the symptoms of individuals with anxiety and/or depressive disorders will occur after eight or twelve weeks of RT.

3.2.3 Recruitment of participants: inclusion and exclusion criteria

A convenience sampling strategy was used to recruit as many participants as possible from the different settings. During a five month period from February until June 2009, adult psychiatric outpatients, adult psychiatric inpatients and adults of both sexes between 18 and 65 years with anxiety and/or depressive symptoms were invited to take part in the study. Excluded from the study were patients: 1) with psychiatric disorders and psychological symptoms other than depressive and/or anxiety disorders; 2) who had somatic contra-indications to running (e.g. cardiovascular diseases) and 3) who already participated in regular aerobic exercise or overuse it. The exclusion criteria were drawn up to prevent physical or psychological danger. The age limit was chosen in order to recruit patients likely to be active on the labor market.

The running therapists and the public were informed of the purpose of the RT intervention and the inclusion and exclusion criteria through a leaflet on Internet (see appendix two) and around the buildings of the physiotherapy and psychologists practices. Recruitment also occurred via referral from general practitioners, psychiatrists or psychologists. Participants were referred or came directly to the running therapist, who determined if the patient fulfilled the inclusion criteria and none of the exclusion criteria. After the selection round, the anxiety and/or depressive symptoms were measured before and after the RT intervention by using the Symptom Checklist-90-Revised (SCL-90-R) data scores.

3.2.4 Characteristics of RT intervention: duration, frequency, intensity, form, time and location

3.2.4.1 Duration, frequency and intensity

The RT intervention lasted for eight or twelve weeks, depending on the amount of sessions (two or three) per week. The duration of the intervention conformed to the typical duration of exercise interventions in psychological literature (around 10-12 weeks) and reflected the minimum period necessary for demonstrable cardiovascular conditioning (Salmon, 2001). Each training session consisted of ten to fifteen minutes of warm-up and cooling-down and was scheduled to last 60 to 90 minutes. Training sessions were performed under supervision of one or two running therapists. Participants were encouraged to complete one session per week on his/her own. In total 24 training sessions were completed during this intervention:

- Two group training sessions per week under supervision and one individual training session per week for a period of eight weeks OR
- One group training session per week under supervision and one individual training session per week for a period of 12 weeks.

Thus, the RT intervention consisted of twelve respectively sixteen training sessions under supervision. This is approximately the number of physiotherapy treatment sessions that patients in the Netherlands can declare on their health insurance (Verzekering Fysiotherapie 2009).

The intensity of the RT sessions was low to moderate, which conformed to the aerobic heart rate zone that represents 70 to 80 per cent of the maximum heart rate. The intensity of the training was measured by the Talk Test (TT) to secure that the participants were exercising in the prescribed heart rate interval.

The Talk Test is a self-reported subjective method for prescribing cardiorespiratory exercise intensity on the basis of the ability of an individual to carry on a conversation during exercise. This method entailed maintaining an intensity of exercise at which the person can "just respond to conversation" (Persinger et al., 2004: page 1632). The advantage of the TT method is its simplicity and its ability to closely reflect the actual heart rate. A disadvantage is the absence of appropriate upper and especially lower limits to produce cardiorespiratory fitness.

3.2.4.2 Form: individually or group basis

The RT intervention took place in a group with a minimum of two and a maximum of eight persons under the supervision of one or two running therapists.

3.2.4.3 Time and location

The RT took place at different times and locations. Participants of physiotherapy practice "Fysiotherapie & Sport van Woerkom" met twice on Tuesday and Thursday from 11:00 till 12:00 o'clock in Health Centre "De Kroonsteen" in Malden. The training sessions took place outdoors in the forest or neighborhood. The participants of the Mental Health Care Institution "De Roerdomp" met twice a week on Monday, Wednesday or Friday from 14:30 till 15:30 o'clock. The training sessions took place outdoors in park in park "Hoog Zandveld. The participants of the Mental Health Care Institution "De Gelderse Roos" met twice a week on Monday from 15:00 till 16:30 o'clock at Sportcentrum Valkenhuizen Arnhem and Thursday from 15:30 till 17:00 o'clock at Nationaal sportcentrum Papendal Arnhem. The training sessions took place outdoors on an athletics track. The participants of "De Psychologenpraktijk" met twice a week on Monday and Wednesday evenings from 19:00 till 20:00 o'clock. The training sessions took place outdoors on an athletics track of athletic society AV Sprint Breda. All patients were responsible for transportation themselves to the RT.

Table 2: Characteristics of the Running Therapy sessions in four settings: physiotherapy practices of two Health Centers, one Mental Health Care Institution and one psychologists practice

CHARACTERISTICS RUNNING THERAPY SESSIONS	PHYSIOTHERAPY & SPORT VAN WOERKOM	DE ROERDOMP	DE GELDERSE ROOS	DE PSYCHOLOGEN PRAKTIJK
Form	- Individually - Group	- Group	- Group	- Group
Days of RT	- Tuesday - Thursday	- Monday - Wednesday - Friday	- Monday - Thursday	- Monday - Wednesday
Time of RT	11:00-12:00	14:30-15:30	15:00-16:30	19:00-20:00
Amount of RT per week	2	2	2	2
Location	Outdoors: - Forest - Neighborhood	Outdoors: - Park	Outdoors: - Athletics track	Outdoors: - Athletics track

3.2.5 Measurements: Symptom Checklist-90-Revised

The Symptom Checklist-90-Revised (SCL-90-R) was used to measure the anxiety and/or depressive symptoms before and after the RT intervention.

The SCL-90-R is a widely used measurement instrument to screen for a broad range of psychological problems and symptoms of psychopathology with a time reference of "the past seven days including today." It consists of a 90 five point Likert type items of self-report inventory that range from "not at all" (0) to "extremely" (4). The SCL-90-R provides three global distress indices, nine primary symptom dimensions and six norm groups for each sex, which can be found in table three. The global distress indices are designed to measure: overall psychological distress (GSI); the intensity of symptoms (PSDI) and to report a number of self-reported symptoms (PST) (Arrindell and Ettema, 1986).

The SCL-90-R scores of the 90 items can be imported in the computer program STM 2.1. This program converts the raw SCL-90-R scores for each of the nine symptom dimensions into standardized SCL-90-R scores, which contains the average rating given to the symptoms of that dimension. Subsequently, the standardized scores of each symptom dimension can be compared with six norm groups by using an ordinal scale that range from "very low" (1) to "extremely high" (7).

Table 3: The SCL-90-R global distress indices, primary symptom dimensions and norm groups

GLOBAL INDICES	SYMTOM DIMENSIONS	NORM GROUPS
1. The Global Severity Index (GSI) 2. The Positive Symptom Distress Index (PSDI) 3. The Positive Symptom Total (PST)	1. Somatisation (SOM) 2. Obsessive-Compulsive (O-C) 3. Interpersonal Sensitivity (I-S) 4. Depression (DEP) 5. Anxiety (ANX) 6. Hostility (HOS) 7. Phobic Anxiety (PHOB) 8. Phobic Anxiety (PHOB) 9. Psychoticism (PSY)	1. Psychiatric inpatients 2. General population 3. Chronic pain patients 4. Clinical addicts 5. First line clients 6. Clients from doctor's practices

Many studies have been conducted to demonstrate the reliability, validity, and utility of SCL-90-R (Pearson Education, 2008). Reliability assessment of the subscales has yielded internal consistency, high concurrent validity with other instruments (e.g. HAM-D) and high construct validity. Furthermore, SCL-90-R was shown to be sensitive to change in a broad variety of clinical and medical contexts (Martinez et al., 2005).

3.2.6 Procedure

All patients who met the inclusion criteria were assigned to the RT intervention. The baseline assessment consisted of the measurement of the SCL-90-R (pre-test). Before the baseline assessment, the following steps took place during the intake phase:

1) The running therapist and the participant became acquainted with each other and the running therapist clarified the content of the RT intervention to the participant;
2) The referral of the participant was assessed. In the most ideal situation the referral of the participant consisted of: a description of the symptom and/or diagnosis; an overview of the treatment history; information about the physical wellbeing; possible medication intake and the aim of the general practitioner regarding the RT intervention (Bakker and van Woerkom, 2008).
3) A written informed consent was signed by the participant (see appendix three) at baseline.

In this way, data about participants' biological, psychological and physical determinants were collected during the intake phase before the start of the RT intervention.

The researcher sent the SCL-90-R questionnaires (including return envelopes) by post to the running therapists one week before the start of the RT intervention. The running therapists were requested, conforming to the scientific protocol (see appendix four), to hand-out the SCL-90-R twice: during the intake phase, which is before the first RT session (pre-test), and three to five days after the last (24th) RT session (post-test). The measurement of the SCL-90-R took place individually, preferably in the afternoon.

The SCL-90-R was completed by the participants with a paper-and-pencil method in ten to fifteen minutes. The running therapists were requested to return the two SCL-90-R questionnaires (pre-test and post-test) of each participant with confidentially within three days after completion to the researcher of this study.

Table 4: Data collection scheme during the Running Therapy intervention of eight weeks

WEEK → MEASUREMENT↓	**COMPLETION TIME**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Maximum duration measurement intake phase	***30 min.***	***x***							
Acquaintance	5	*x*							
Referral assessment	5	*x*							
Signing informed consent	5	*x*							
SCL-90-R (pre-test: T1)	15	*x*							
Maximum duration intervention (X) with 2 sessions each week under supervision of a running therapist and 1 session facultative by participant	***36 hours***	***x***	***x***	***x***	***x***	***x***	***x***	***x***	***x***
Duration training session each time	60-90	*x*	*x*	*x*	*x*	*x*	*x*	*x*	*x*
Maximum duration re-measurement	***15 min.***								***x***
SCL-90-R (post-test: T2)	15								*x*
MAXIMUM DURATION ↓	**Circa 37 hours**								

3.2.7 Statistical analysis

By using the SCL-90-R, the difference in participants' anxiety and depressive symptoms were measured before and after the RT intervention. When the two SCL-90-R questionnaires (pre-test and pos-test) of each participant were received, they were imported in the computer program STM 2.1. This program converted the raw SCL-90-R scores into standardized SCL-90-R scores. Subsequently the program transformed these standardized SCL-90-R scores in categories as compared with the general population by using an ordinal scale that range from "very low" (1) to "extremely high" (7). An example of one participant (Pt-ID: 01) is depicted in figure one.

Figure 1: The two SCL-90-R scores obtained before and after treatment of a participant (Pt-ID: 01).

	STANDARDIZED SCL-90-R SCORE	**CATEGORIES as compared with GENERAL POPULATION**
PRE-TEST ANXIETY	17	High (6)
POST-TEST ANXIETY	13	Average (4)
PRE-TEST DEPRESSION	38	Extremely high (7)
POST-TEST DEPRESSION	22	Average (4)

When the difference in participants' anxiety and depressive symptoms were computed, they were imported in SPSS 15.0 for Windows. The Paired Samples T-Test was used to determine if there was a significant difference between the pre-test versus post-test standardized SCL-90-R anxiety and depression scores. Statistically significant levels were reported for p-values less than or equal to 0.05. Furthermore, the non-parametric Wilcoxon Test for Two Related Samples was used to determine if participants ended up in a better or worse category after the RT intervention. Clinically significant levels were reported for p-values less than or equal to 0.05. Moreover, Cohen's d for Paired Samples T-Test and Pearson's r was used to measure the effect size of RT on the standardized SCL-90-R anxiety and depressive scores. The effect sizes of the Paired Samples T-Test (Cohen's d) and the non-parametric Wilcoxon Test for Two Related Samples (Pearson's r) were interpreted by using the following rules (Miles and Banyard, 2007):

- Large effect size: d or r ≥ 0.8
- Medium effect size: d or r = 0.5
- Small effect size: d or r ≤ 0.3

Table 5: Assumptions underlying the Paired Samples T-Test and Cohen's d for the Paired Samples T-Test according to Miles and Banyard (2007)

PAIRED SAMPLES T-TEST	COHEN'S D for PAIRED SAMPLES T-TEST
1. Only the matched pair can be used to perform the t-test	1. Both variables should be dependent of one another
2. Both variables should be normally distributed	
3. The variance of the two samples is the same	
4. Observations must be independent of each other	

It should be noticed that the used one group pre-test post-test design does not allow the conclusion that RT is responsible for any significant difference in the SCL-90-R scores, since the design lacks a control group.

3.3 Qualitative study: Rationales for participation in Running Therapy

To examine the question: *"What are the rationales for individuals to choose for Running Therapy?"* semi-structured interviews were used.

3.3.1 Introduction and justification

The rationales of individuals to choose for RT were examined in order to gain detailed information about participants' thoughts, feelings and experiences about RT. The used qualitative research method aimed to improve the understanding of the participants under study that might lead to the recognition of rationales that, up to this point, were neither considered nor expected. The results of the interviews were used to provide context to the results of the quantitative study.

3.3.2 Recruitment of interviewees

A convenience sampling strategy was used to recruit participants to investigate the rationales of individuals to choose for RT. Individual interviews took place with a total number of eleven adult patients of physiotherapy practice "Fysiotherapie & Sport van Woerkom" from Health Center "De Kroonsteen" (7) and the Mental Health Care Institution "De Gelderse Roos" (4). During a two month period from May until June 2009, patients who met the inclusion criteria of the RT intervention (see paragraph 3.2.3) were invited to take part in this study. Patients of both sexes between 18 and 65 years with comorbid stress related psychiatric disorders and psychological symptoms other than depression and/or anxiety (e.g. burn-out) were also invited to take part in the study. Excluded from the study were patients with insufficient knowledge of the Dutch language.

The interviewees of “Fysiotherapie & Sport van Woerkom” and “De Gelderse Roos” were informed of the purpose of the interviews and the inclusion and exclusion criteria during the sessions of the RT intervention, in which the researcher participated as running therapist. Interviewees did not receive an incentive. Written informed consent was obtained from all interviewees before the start of the interview (see appendix five). After gaining permission of the participants, interviews were audio recorded in combination with written notes.

3.3.3 Procedure and setting

The individual interviews were held before or after the RT sessions, since the topics of the interview dealt with personally sensitive or socially influenced issues. Interviews with interviewees of “Fysiotherapie & Sport van Woerkom” were held in the morning before the sessions in a therapy room of the physiotherapy practice in Health Centre “De Kroonsteen”. Interviews with interviewees of “De Gelderse Roos” were held in the afternoons after the RT sessions at the athletics track of Sportcentrum Valkenhuizen in Arnhem. The environment of the interviews was chosen in order to create a relaxed and informal atmosphere.

The reception staff member of “Fysiotherapie & Sport van Woerkom” was alerted to the interviewees’ expected arrival. The interviewees were offered a drink of tea, coffee or water before the start of the interview. The therapy room of the physiotherapy practice, which was used as the interview room, was private and free of interruption and distraction. The researcher and interviewee sat in chairs face to face each other. In this way the interviewee was able to see the researcher’s face. With one interviewee this was especially important, since he had hearing difficulties and partly relied on lip-reading to “hear” what was being said. The researcher was not sitting across a desk, since this might conveyed a feeling of status and the physical barrier might created a psychological barrier which made rapport harder to establish.

The researcher and the interviewee of “De Gelderse Roos” chose a quite place on the ground of the athletics track nearby the high jump pit to hold the interview, which took place after the RT session. The running therapist of “De Gelderse Roos” was alerted to the researchers’ expected arrival at the athletics track. The researcher became acquainted with the participants of the RT group, since she introduced herself before and participated as co-running therapist during the RT sessions. In this way the researcher attempted to create a relaxed and informal atmosphere with the interviewees before the start of the interview.

3.3.4 Conducting interviews

The interviews were conducted and performed by the researcher of this study.

After welcoming the interviewee, general questions were asked about age, education level, employment status, health status and use of psychotropic medication. Interviewees were also asked to reflect on their expectations and experiences regarding RT. Moreover, questions about interviewees’ knowledge and information searching behavior and referral to RT were asked. The last two questions functioned as transition to the second part of the interview. Therefore, the information gathered from these questions was not analyzed in the results.

The second part of the interview was the most relevant, since the interviewees were asked about their rationales to choose for RT. The researcher attempted to ask in-depth questions to improve the understanding of the interviewees. In the final part interviewees were asked how many RT sessions they had accomplished and how many they still had to do. Finally they were asked how they thought about the way to continue with running after the intervention. These final questions were asked to complete the interview. Therefore, the information gathered from these questions was not analyzed in the results. A topic list of the interviews can be found in the table six.

Table 6: Interview topic list

PART ONE: INTRODUCTION	**QUESTIONS**
General	- How old are you? - What is the highest education you have received? - What do you do for a living? - What kind of health symptoms do you have? - Do you use psychotropic medication?
Experience RT	- How is it going with respect to RT?
Expectations RT	- What did you expect RT would do for you regarding your symptoms?
Knowledge & information searching behavior	- What information did you receive before you started with RT? - What did you know about RT before you started with it?
Referral	- Who or whom referred you to RT?
PART TWO: CORE	**QUESTIONS**
Rationales to choose for RT	- What made you decide to participate in RT? - Subsequently in-depth questions
PART THREE: FINAL	**QUESTIONS**
	- How many RT sessions have you accomplished? - How many RT sessions do you still have to do? - How do you think to continue running after the RT intervention?

3.3.5 Domain analysis

A complete transcription of each interview was carried out in Microsoft Office Word 2003. Each transcript was read and re-read by the researcher in order to gain an overall understanding of the patients' thoughts, feelings and experiences, to identify primary domains and to construct subcategories within these domains. All eleven transcripts were evaluated by the researcher and a co-Master student Public Health and Society, so that the analysis could be refined through discussion. This process was also used to meet the requirements of investigator-triangulation regarding the expansion of subjective interpretations. The co-Master student has signed a confidentiality agreement to guarantee participants' anonymization before she contributed to the evaluation of the transcripts.

To evaluate the transcribed interviews, domain analysis was applied. First, the key topics or primary domains raised by the interviewees were identified. After the identification of the primary domains, the grouping of more detailed topics within each of these domains resulted in subcategories, which informed the development of themes. Subsequently, specific text segments were assigned to the individual subcategory and then condensed and abstracted by bundling and paraphrasing the text. The reduced data made up the basis for the themes and the inter-individual comparison table, which focused on similarities and contrasts. A description of the primary domains can be found in the results (see paragraph 4.3).

4 RESULTS

4.1 Quantitative study: Running Therapy Intervention

4.1.1 Participants' baseline characteristics and adherence

A total of nine participants were finally included in the RT intervention. Among the nine participants, eight completed the study. Sport injuries were not mentioned as reason for dropout. There were no differences in disorder, psychotropic medication, age or sex at baseline between the study completers and the person who dropped out.

From the eight participants, all suffered from mood disorder of which one comorbid major depressive disorder and anxiety, one major depressive disorder and psychotic features, five depressive disorders not otherwise specified of which three comorbid with anxiety and one generalized anxiety disorder. The median age was 38 years, ranging from 22 to 61. Four participants were female, four were male. Five of the eight participants used psychotropic medication to tackle their symptoms.

4.1.2 Changes in SCL-90-R anxiety and depression scores

When analyzing the SCL-90-R, no missing data were observed. The standardized SCL-90-R anxiety and depression scores before and after the intervention are depicted in table seven.

Table 7: Pre- and post-test data with respect to the standardized SCL-90-R anxiety and depression scores

PT-ID	PRE-TEST ANXIETY	POST-TEST ANXIETY	DIFFERENCE	PRE-TEST DEPRESSION	POST-TEST DEPRESSION	DIFFERENCE
01	17	13	-4	38	22	-16
02	28	23	-5	45	31	-14
03	34	31	-3	69	63	-6
04	21	16	-5	34	22	-12
05	15	11	-4	22	17	-5
06	30	20	-10	59	37	-22
07	12	11	-1	19	25	6
08	10	10	0	21	22	1
Mean	**20.88**	**16.88**	**-4**	**38.38**	**29.88**	**-8.5**

The RT gave rise to a reduction in the standardized SCL-90-R anxiety score for seven of the eight participants (87.5%), with the exception of one participant (Pt-ID: 08) who did not show any difference. Regarding the standardized SCL-90-R depressive score, it can be said that six of the eight participants (75%) have shown a reduction. Two participants (Pt-ID: 07 and 08) have shown an increase in the standardized SCL-90-R depressive score. However, the mean standardized SCL-90-R anxiety (-4) and depression (-8.5) score have shown a reduction.

The Paired Samples T-Test revealed a statistically significant reduction in participants' anxiety ($T = 3.742$; $P = .007$) and depressive ($T = 2.597$; $P = .036$) symptoms with respect to the standardized SCL-90-R anxiety and depressive scores. Moreover, Cohen's d for Paired Samples T-Test revealed a large effect size ($d = 1.32$) of RT on the standardized SCL-90-R anxiety scores, as an effect size of $d \geq 0.8$ was considered large in this study. Nonetheless, the effect size of RT on the standardized SCL-90-R depression scores was somewhat lower ($d = .92$), but still considered large, since $d = \geq 0.8$.

Table eight depicted participants' standardized SCL-90-R anxiety and depression scores in categories, as compared with the general population, by using the following ordinal scale:
1 very low - 2 low - 3 below average - 4 average - 5 above average - 6 high - 7 extremely high.

Table 8: Pre- and post-test data with respect to the standardized SCL-90-R anxiety and depression scores in categories as compared with the general population (norm group II)

PT-ID	PRE-TEST ANXIETY	POST-TEST ANXIETY	DIFFERENCE	PRE-TEST DEPRESSION	POST-TEST DEPRESSION	DIFFERENCE
01	6	4	-2	7	4	-3
02	7	7	0	7	6	-1
03	7	7	0	7	7	0
04	6	6	0	6	4	-2
05	6	3	-3	4	3	-1
06	7	7	0	7	6	-1
07	4	3	-1	3	6	3
08	3	3	0	4	4	0
Mean	**5.75**	**5**	**-.75**	**5.63**	**5**	**-.63**

When the standardized SCL-90-R anxiety score was compared with the anxiety score of the general population, it can be said that three participants (37.5%) ended up in a better classification after RT treatment. The other five participants (62.5%) stayed in the same category. By comparing the standardized SCL-90-R depression score with the depression score of the general population, it can be said that five of the eight participants (62.5%) ended up in a better classification, whereas two participants (Pt-ID: 03 and 08) stayed in the same category. One participant (Pt ID: 07) ended up in a worse classification, since s/he showed an increase in the depression score. However, the mean standardized SCL-90-R anxiety (-.75) and depression (-.63) scores have shown a reduction.

The non-parametric Wilcoxon Test for Two Related Samples did not reveal a clinically significant reduction in participants' anxiety ($Z = -1.604$; $P = .109$) and depressive ($Z = -1.063$; $P = .288$) symptoms with respect to the standardized SCL-90-R anxiety and depressive scores that were compared with the scores of the general population. Moreover, Wilcoxon Test for Two Related Samples revealed a medium effect size ($r = .40$) of RT on the SCL-90-R standardized anxiety scores that were compared with the anxiety scores of the general population, as an effect size of $r = 0.5$ was considered as medium in this study. The effect size of RT on the standardized SCL-90-R depressive scores that were compared with the depressive scores of the general population was lower ($d = .27$), and considered as small, since $r = \leq 0.3$.

4.2 Conclusion

On average the SCL-90-R anxiety and depression scores had decreased statistically significant after eight or twelve weeks of RT treatment. However, this improvement was not clinically significant: on average, the improvements were not big enough to result in a better category compared to the general population.

4.3 Qualitative study: Rationale's for participation in Running Therapy

First, a brief description of the eleven interviewees' characteristics is given. Subsequently, the results of individuals' rationales to choose for RT are presented according to primary domains and themes.

From the eleven interviewees, nine suffered from mood disorder of which one from bipolar disorder, one had comorbid bipolar disorder and anxiety, two from depressive disorder not otherwise specified, two had comorbid depressive disorder not otherwise specified and anxiety, one had comorbid depressive disorder not otherwise specified and ADHD, one had comorbid major depressive disorder and anxiety and one had major depressive disorder with psychotic features. Moreover, one interviewee suffered from adjustment disorder with depressed mood and one from borderline personality disorder. The median age was 39 years, ranging from 22 to 61. Seven interviewees were female, four were male. Regarding school education four interviewees had finished secondary school, two had a MBO degree, four had a Bachelor degree and one interviewee had a Master degree. At the time of the interview, all interviewees had been notified of their health status and had started induction RT. According to the interviewees' readiness to communicate, the duration of the interviews ranged from ten to twenty five minutes, corresponding to a size between 782 and 2795 words (mean: 1630).

The primary domain of this qualitative study was concerned with the rationales for individuals to choose for RT. The other domains of the interviews can be found in table nine.

Table 9: Identification of primary domains

PRIMARY DOMAINS
Expectations about Running Therapy (= before engaging in Running Therapy sessions)
Experience in Running Therapy (= during the Running Therapy sessions)
Accessibility of running
Side effects of psychotropic medication
Running alone versus running in groups
Running Therapy appointment
Support to start and maintain Running Therapy

The presentation of the findings regarding the rationales for individuals to choose for RT was organized according to the following five themes:

- Mental health benefits (4.3.1);
- (Physical) running benefits (4.3.2);
- Reducing or quitting psychotropic medication (4.3.3);
- Group pressure and contract (4.3.4);
- Support of the social environment (4.3.5).

These five themes were the result of grouping more detailed topics within each of the primary domains in subcategories. Within the themes "mental health benefits" and "(physical) running benefits", a distinction was made between expectations (= before engaging in RT) and experiences (= during RT). Moreover, a distinction was made in before and/or during within the theme "support of the social environment", since support can be given before the start of the first RT session and/or during the RT session to maintain RT.

The subjoined study findings provided insight into the rationales for individuals to choose for RT. Quotes reproduced in this thesis had been labeled with the patients ID number (Pt-ID).

4.3.1 Mental health benefits

Some participants did not expect mental benefits of RT and were skeptic about it. One participant argued: *"Ik was heel sceptisch in het begin, zo van: het zal wel. Maar ik vind echt: het werkt echt: ik word vrolijker, ik krijg meer zin in dingen." (Pt-ID: 11).* A number of participants stated that they chose for RT, because they expected that RT could help them to relax and reduce and manage anxiety, depressive and burn-out symptoms. Quotes included: *"Runningtherapie is een manier om tot rust te komen: dat was eigenlijk wel nodig. Ik ben nu wat rustiger en minder gestrest." (Pt-ID: 4)* and *"Mijn klachten waren vooral stress of gewoon stress gerelateerd, zoals angst, van: Ga ik het allemaal wel redden of gaat het allemaal wel lukken?"…"Ja, het is echt die ontspanning: gewoon even uit je hoofd en in je lichaam: gewoon bezig zijn. En niet zomaar met de afwas bezig zijn, want dat is ook bezig zijn, maar dat is anders dan meer van je lichaam vragen." (Pt-ID: 7).*

Although not all participants expected mental health benefits before participating in RT, analysis revealed that participants experienced mental benefits during RT, such as feelings of pleasantness. This is illustrated by the quote: *"Je gewoon beter voelen en prettiger voelen, omdat ik heel erg tob." (Pt-ID: 1).* An increase in self-confidence and assertiveness was another mental benefit that participants experienced during participating in RT. This was highlighted by quotes, such as: *"Je krijgt wat meer zelfvertrouwen. Je voelt je gewoon lekkerder. Ik weet niet. Het is gewoon een gevoel. En de kick die je hebt als je gelopen hebt. Dat vind ik ook: dat geeft je natuurlijk ook zelfvertrouwen. De kick dat je het kan." (Pt-ID: 1)* and *"Het lijkt dan net of mijn remmen even weg zijn en dat ik heel duidelijk kan zeggen wat ik vind, net alsof er een stuk spanning weg is en dat ik daardoor assertiever kan zijn. Dat vind ik best een openbaring, want ik had helemaal niet gedacht dat dat het zou opleveren. Je merkt: je wordt niet alleen lichamelijk sterker, maar psychisch ook." (Pt-ID: 5).*

As the participants completed more RT sessions, all participants reported it as a quite enjoyable activity to do. Participants agreed that RT gave some structure to their daily life. Some participants faced troubles in managing to come to RT twice a week due to practical reasons or one's mental state (e.g. *"De ene keer beter dan de andere keer, maar ik ben blij dat ik er mee begonnen ben." (Pt-ID: 8)* and *"Ik vind wel zwaar nog steeds zwaar, maar ik merk wel dat ik me na de runningtherapie goed voel." (Pt-ID: 11)*). Nonetheless, all participants experienced satisfaction when they accomplished the RT session (e.g. *"Je gaat je gewoon beter voelen als je actief bezig bent. Ik merk nu ook, zeker als je slechte dagen hebt gehad, en ik doe weinig, ben passief, dat ik dan in ieder gaval weer één dag in de week iets heb gedaan wat op het lijstje stond van de dingen die moeten gebeuren die week. Dat geeft een positief gevoel." (Pt-ID: 6)*).

4.3.2 Physical / running benefits

Analysis revealed that participants chose for RT because they expected to improve their physical health by running, such as increasing cardiovascular endurance and muscle strength. Quotes included: *"Ik wilde eigenlijk mijn conditie verbeteren en een stukje spanning van mijn spieren weg krijgen door me in te spannen en daarna de ontspanning in mijn lichaam te kunnen voelen." (Pt-ID: 5)* and *"Voor mij was het wel een motivatie om iets aan sport te doen."…"Ik wilde ook gewoon wat met mijn lichaam gaan doen.*

Gewoon weer bezig te zijn." (Pt-ID: 6). Two participants reported that they chose for RT because they wanted to start with exercise and control weight: *"Ik ben nu al net over de (…), ik moet eens wat aan beweging gaan doen, want dat deed ik eigenlijk nooit."… "ik word ouder en ik word wat dikker: ik moet wat aan mijn gezondheid gaan doen."…"Toen zei ik tegen mijzelf: ja, ik moet dat gewoon eens gaan proberen." (Pt-ID: 3)* and *"Ik heb gekozen voor runningtherapie om conditie op te bouwen en af te vallen" (Pt-ID: 4).* The easy accessibility of running was for one participant also a rationale to choose for RT: *"Dat laagdrempelige sprak mij toen echt aan van rennen."… "Je gaat gemakkelijk de voordeur uit, je trekt wat aan, je gaat hardlopen en je komt terug en je bent klaar." (Pt-ID: 3).* This participant also experienced that running increased her energy, which is another benefit of running: *"Ik wist toen nog niet dat juist als je je zo moe voelt door de burn-out, dat als je gaat hardlopen dat je daarvan energie krijgt en dat je moeheid kan verdwijnen. Toen redeneerde ik heel simpel: ik ben nu al zo moe, ik heb geen energie meer, dus ik kan ook niet meer gaan hardlopen. Ik wist toen niet dat het anders werkt." (Pt-ID: 3).*

A positive experience in the past was another rationale for a number of participants. Quotes included: *"Hardlopen kende ik al van de sportschool op een hardloopband, dat lag mij wel, dat vond ik wel leuk om te doen." (Pt-ID: 6)* and *"Ik heb vroeger ook hardgelopen, tien jaar, dat ging vrij goed. Dat was voordat ik in de psychiatrie zat. En daarom wilde ik het ook weer oppakken, omdat ik het leuk vond." (Pt-ID: 9).*

4.3.2 Reducing or quitting psychotropic medication

Three of the seven participants who used or had used psychotropic medication reported that they chose for RT because they want to reduce or quit psychotropic medication due to the perceived negative side effects. This was illustrated by the quotes: *"Ik wilde gewoon van de medicijnen af, want ik voelde me steeds beroerder: het hele lichaam wordt helemaal onderdrukt." (Pt-ID: 2)*; *"Ik wil van mijn medicijnen af en dat is best wel akelig als je dat zonder ruggensteuntje moet doen." (Pt-ID: 5)* and *"Ik wilde onderhand van die medicatie af door de vervelende bijwerkingen." … "Ik merk ook dat in corpore in sano, maar ik denk dat het ook komt door de combinatie van de halvering van de medicijnen, want één van de nadelen daarvan is dat ik heel moeizaam op gang kom, dat ik sloom was, traag reageerde. Sinds ik dat gehalveerd heb in combinatie met dat hardlopen, heb ik het idee dat dat een stuk verbeterd is. Dat ik me enigszins wat alerter voel en minder slaperig." (Pt-ID: 10).*

4.3.4 Group pressure and the Running Therapy appointment

Several participants reported that the RT appointments positively contributed to continued participation. Quotes included: *"Ik maak een afspraak om te gaan hardlopen en dat werkt wél." (Pt-ID: 7)* and *"Als er geen stok achter de deur is, dan heb ik het heel moeilijk: dan doe ik eigenlijk niet zo veel." (Pt-ID: 11).* Group pressure was another rationale for the participants to start and maintain RT. Quotes included: *"Je hebt een stok achter de deur, je gaat in een groepje." (Pt-ID: 5); "Voor mij is dat een hele goede stap om dat in groepsverband te doen, want dan voel ik me meer verplicht om te komen." (Pt-ID: 6);* and *"Ik het wel prettig in een groepje hardlopen: het stimuleert en er wordt verwacht dat je er op een bepaald tijdstip bent en dat helpt echt wel." (Pt-ID: 10).*

4.3.5 Support of social environment

All participants reported that the social environment – the health professional and the family – provided them financial, emotional and/or physical support before and during the RT. This was illustrated by the quotes: *"Ik vraag in ieder geval mijn man of hij mee wil lopen. En die zei ook meteen: ja, dat wil ik wel.*

Toen zijn we frequent, drie keer in de week gaan lopen." (Pt-ID: 1); "Ze zeggen tegen mij dat ik daaraan deel moet nemen." (…) "omdat men mij duidelijk had gezegd: je kunt daar wat uithalen." …. "Ik loop wel vaker met mijn zoon en dat is ook zo'n jongen die dan zegt: kom op mam, je kunt het mama, nog even en dat soort dingen. Soms loop ik ook alleen, maar dat vind ik wel moeilijk, want dan ben je eerder geneigd om te stoppen." (Pt-ID: 8) and *"De eerste keer is er ook iemand mee gegaan, mijn broer, omdat ik niet alleen wilde gaan." (Pt-ID: 011).* The participants of the RT group also provided support to each other to maintain the RT sessions. Quotes included: *"Ik vind deze groep heel fijn. Ja, gewoon, omdat ze je wel begrijpen: je hoeft je ook niet groot te houden." (Pt-ID: 8); "De sociale factor in het hardlopen, vind ik ook prettig." (Pt-ID: 9)* and *"Als ik alleen loop, dan blijf ik toch veel denken, dan blijf ik toch malen. En als ik in een groep loop, dan kan ik het even loslaten." (Pt-ID: 11).* Support of the participants of the RT group in combination with personal challenge was another rationale to maintain the RT. Quotes included: *"Met de runningtherapie merk ik dat ik uitdaging heb, zo van: kom op nu, nog een klein stukje of nog even wat harder, omdat je niet alleen bent." (Pt-ID: 7).*

Figure 2: Participants' rationales to choose for Running Therapy according to the five themes. The amount of times participants mentioned each rationale can be found between brackets.

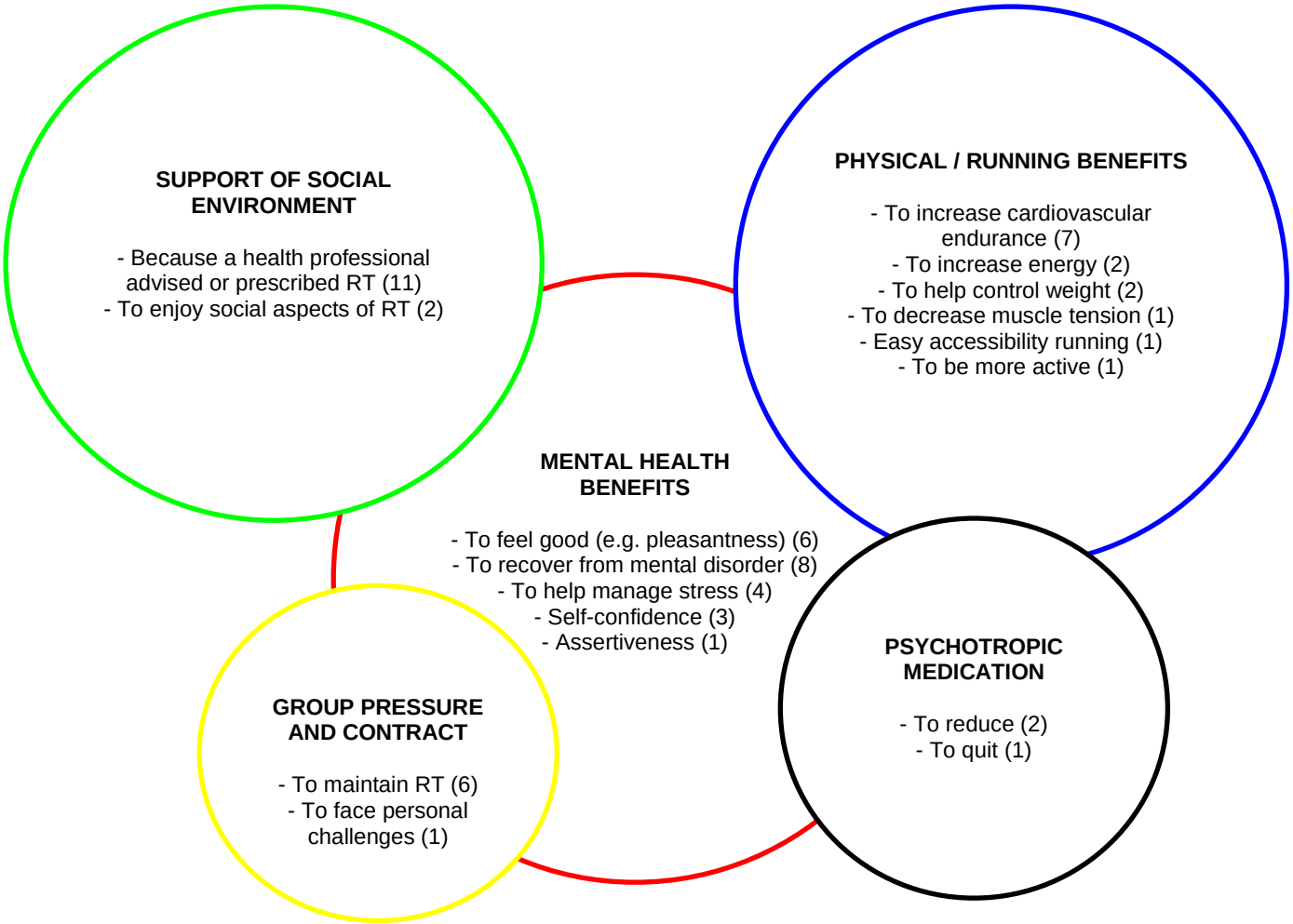

Table 12: Inter-individual comparison table: themes and participants' similarities and contrasts

Pt-ID	1. MENTAL HEALTH BENEFITS: expected (1) or experienced (2)	2. PHYSICAL / RUNNING BENEFITS: expected (1) or experienced (2)	3. PSYCHOROPIC MEDICATION: aim to reduce (1) or quitted (2)	4. GROUP PRESSURE & CONTRACT	5. SUPPORT OF SOCIAL ENVIRONMENT: before (1) and/or during (2)
1	- Feelings of pleasantness (2) - Increase in self-confidence (2)	- Increase cardiovascular endurance (1+2)	Did not use psychotropic medication.	Group pressure stimulated to maintain RT	- Psychologist (1) - Running therapist (1+2) - Husband (1+2) - Participants RT group (2)
2	- Feelings of pleasantness (2) - Depressive & stress reduction (1+2) - Relaxation (1+2)	-	Did use psychotropic medication in the past & perceived possible negative side effects (2)	-	- Psychologist (1) - Running therapist (1+2)
3	- Feelings of pleasantness (2) - Depressive & burn-out reduction (1+2)	- Increase cardiovascular endurance (1+2) - Increase energy (2) - Weight control (1) - Easy accessibility	Did not use psychotropic medication.	-	- Psychologist (1) - Running therapist (1+2) - Husband (1+2) - Participants RT group (2) - Highly self motivated.
4	- Feelings of pleasantness (2) - Depressive and stress reduction (1+2) - Relaxation (1+2)	- Increase cardiovascular endurance (1+2) - Weight control (1)	Did not use psychotropic medication.	-	- Psychologist (1) - Running therapist (1+2) - Participants RT group (2)
5	- An increase in self-confidence & assertiveness (2) - Depressive and stress reduction (1+2) - Relaxation (1+2)	- Increase cardiovascular endurance (1+2) - Decrease muscle tension (1+2)	Did use psychotropic medication & perceived possible negative side effects (1)	Group pressure stimulated to maintain RT	- Social worker (1) - Running therapist (1+2) - Participants RT group (2)
6	- Feelings of pleasantness (2)	- To be more active (1+2)	Not applicable, although psychotropic medication was used.	RT appointment committed to maintain RT	- Running therapist (1+2) - Participants RT group (2)
7	- Relaxation (1+2) - Depressive & stress reduction (1+2)	- Increase cardiovascular endurance (1+2) - Increase energy (2)	Did not use psychotropic medication.	RT appointment & personal challenge committed to maintain RT	- Psychologist (1) - Running therapist (1+2) - Participants RT group (2)
8	- Depressive & anxiety reduction (1+2)	- Increase cardiovascular endurance (1+2)	Not applicable, although psychotropic medication was used.	-	- Psychomotor therapist (1) - Running therapist (1+2) - Son (1+ 2) - Participants RT group (2)
9	- Depressive & anxiety reduction (1+2)	-	Did use psychotropic medication & perceived possible negative side effects (1)	-	- Running therapist (1+2) - Participants RT group (2)
10	- Depressive & anxiety reduction (1+2)	- Increase cardiovascular endurance (1+2)	Not applicable, although psychotropic medication was used.	RT appointment committed to maintain RT	- GP (1) - Running therapist (1+2) - Participants RT group (2) - Highly self motivated.
11	- Feelings of pleasantness (2) - An increase in self-confidence (2)	-	Not applicable, although psychotropic medication was used.	RT appointment committed to maintain RT.	- Psychologist (1) - Running therapist (1+2) - Brother (1+2) - Participants RT group (2)

4.4 Conclusion

Participants had mental, physical and social related rationales to choose for RT, which did change over time, probably as a response to being involved in the activity. There were neither remarkable similarities nor contrasts in rationales between participants concerning their age, education level, profession, health status and use of medication. The results seemed to confirm the perceived importance of RT as alternative treatment for mild to moderate and severe depressive and/or anxiety disorders, since several participants who used psychotropic medication and quitted – due to the perceived negative side effects (e.g. sexual dysfunction, fatigue, insomnia, agitation) – subsequently chose for RT as alternative treatment. Moreover, participants' rationales seemed to emphasize the importance of the proactive health professional-patient relationship, which was essential to ensure adherence to RT. The social environment, including the health professionals, the family and the participants of the RT, were part of the social support system that nourished and encouraged participants' initiation and continuation in RT.

5 DISCUSSION

This study examined the effectiveness of RT on the symptoms of individuals with anxiety and/or depressive disorders and provided information about the rationales of individuals to choose for RT.

Study results revealed that on average the SCL-90-R anxiety and depression scores had decreased statistically after eight or twelve weeks of RT treatment. However, this improvement was not clinically significant. Although improvements were achieved, the used study design does not allow to speak of a confirmation of the hypothesis that RT is effective in reducing anxiety and/or depressive symptoms. The absence of a control group did not allow the conclusion that RT was responsible for any statistically significant difference and that this reduction was not just, say, the result of passage of time. In addition, the absence of a control group could result that uncontrolled events rather than RT were producing reductions in anxiety and depressive symptoms. The interaction effect of RT with psychotropic medication and/or conventional therapies might be such an event, since the combined impact may be much greater than the simple cumulative impact of each approach. The social support system that nourished and encouraged participants' initiation and continuation in RT, might also be an extraneous event that reduced participants' anxiety and/or depressive symptoms. Moreover, the role of genetic variation among individuals might be an extraneous event, since numerous studies have ascribed the variation in anxious and depressive symptoms to heritable traits (de Moor et al., 2008; Stubbe et al., 2006; Boomsma et al., 2000). Although this study did not offer conclusions about which extraneous events may mediate the reduced anxiety and/or depressive symptoms, they should be taken into account when interpreting the effectiveness of RT.

Psychological, cognitive and physiological mechanisms have been suggested as mechanisms by which aerobic exercise reduced anxiety and/or depressive symptoms in previous studies (e.g. Foley et al., 2008). Study results of the qualitative data and the observations of the researcher during the RT sessions, point towards the possibility that psychological mechanisms – including a high motivation to start and maintain RT, increased self-confidence, feelings of self-efficacy and reduced negative thought patterns – might be responsible for the reductions. In addition, by deciding to participate in RT, depressed patients seems to start to overcome the difficulty in decision-making and problem solving, which could indicate a first sign of recovery. However, definite conclusions about the actual mechanisms responsible for the reported reductions remain unknown. Regarding the impact of the RT intervention it can be said that the effect size ($d = .92$) of RT on the standardized SCL-90-R depressive symptoms was lower than the mean effect size ($d = 1.42$) of the meta-analysis of eleven controlled studies by Stathopoulou et al. (2006) for exercise interventions in the treatment of depression. Although an effect size of $d = .92$ was considered large, caution should be exercised, since the current study was not well controlled. However, the effect size of .92 is still seen as an important finding, as any reduction in depressive symptoms could imply lower socio-economic costs in the society (Wittchen and Jacobi, 2005).

Other important findings were obtained by study results of the qualitative data. Several participants mentioned that they had chosen initially for RT because they expected mental benefits, such as recovering from the mental disorder. However, as cardiovascular endurance improved over time, enjoyment of the social aspects of running became more salient. That exercise motivations may change over time as a

response to being involved in physical activity was pointed out earlier by Markland (1999). It can not be concluded that individuals' rationales to choose for RT, such as because a health professional prescribed this form of exercise, were perceived as controlling and thereby undermining self-determination and leading to a lack of enjoyment of exercise. Results of the quantitative and qualitative study seemed to underline the importance that: participants of RT were ready to change their physical activity behavior; RT was delivered in a group and ongoing social support before, during and after the RT was made available. These findings were consistent with previous studies on the positive correlation between the social support system and exercise participation (Carless and Douglas, 2008).

5.1 Limitations

The present study is subject to several limitations. A first limitation concerns the sample size in the RT intervention and the semi-structured interviews. The number of participants (n=8) in the intervention was small, due to difficulties in recruitment. This results in limited generalizability of the decrease in the standardized SCL-90-R anxiety and depression scores after RT treatment. Although findings of previous studies illustrated that depressed patients had difficulties to start and maintain exercise interventions (Seime, 2007; Ussher et al., 2007; Richardson et al., 2005), this study had less difficulties in participants' retention. There were eight participants, of whom seven were depressed, who completed the intervention by running two or three times per week during eight or twelve weeks. There was only one depressed participant who dropped-out. It is assumed that participants' maintenance in the RT intervention was partly achieved by the role of running therapists' during the training sessions. The small number (n=11) of semi-structured interviews was not seen as a limitation, since within the two groups of interviewees – physiotherapy practice "Fysiotherapie & Sport van Woerkom" and "De Gelderse Roos" – theoretical saturation was already achieved after nine persons. Moreover, the collection of more data did not lead to a substantial increase in insight of individuals' rationales to choose for RT.

The used convenience sampling strategy is a limitation as well. It may have yielded some homogeneity, in that all participants of the quantitative and qualitative part of this study were white middle to upper-middle-class men and women. With regard to all participants in this study being white middle to upper-middle-class, the ability to generalize findings outside the study population seems to be severely limited, especially regarding the effectiveness of RT. This limitation was less severe for the qualitative part of this study, since there was no literature found by the researcher on individuals' rationales to choose for RT at all.

The third limitation contains the role of the researcher as running therapist and interviewee during the time when the RT intervention and the semi-structured interviews took place. The researcher underwent the same runners experience as the participants during the RT sessions, since she was responsible for giving RT. Although the role as running therapist enabled the researcher to develop trust and rapport with the study participants, it may also have colored the participants' thoughts, feelings and experiences about RT. The involvement of the researcher with the participants during the RT intervention, might have affected the study results. In addition, the social interaction of study participants may have had a beneficial effect, since RT was performed in a group setting. Nonetheless, a study done by Blumenthal et al. (2007) has shown that there was no difference in the severity of depressive symptoms between exercising alone or in a group. Future research on RT may need to control for the level of social involvement by examining the effects of the RT form (e.g. alone versus group-based) on response to treatment.

Regarding the qualitative part of this study, a final limitation concerns the data analysis of the interviews that may have been compromised for the reason that the researcher acted as the primary coder in this study. Efforts to minimize this effect included critical discussions with a co-Master student Public Health and Society. Nonetheless, the use of participants' quotes helped the researcher to understand the thoughts, feelings and experiences of the participants about RT.

5.2 Recommendations for future research

This study recommends that RT should be further explored, by taking genetic variation among individuals into account, especially among individuals with no comorbid symptoms (e.g. only generalized anxiety disorders). The absence of a control group in this study, did not allow the conclusion that RT was responsible for reductions in anxiety and depressive symptoms. Therefore, a randomized controlled trial with a 1 factor (two levels: experimental versus control condition) pre-test post-test design is recommended to use for future research. However, the randomized controlled trial lacks a "real life setting" and relies on controlled events instead of naturally occurring events, which was an advantage of the RT intervention in this study (e.g. the usual referral from the general practitioner to supervised RT, the weather conditions during the outdoor RT sessions). Furthermore, the sample size in the RT intervention limited the generalizability of the study results. Based on the study results, a minimum total required sample size of 52 study participants and a minimum required sample size of 26 per group (experimental versus control condition) is recommended for a two-tailed T-Test by using a 2-sided test at alpha = 0.05, a desired statistical power of (1-beta) = 0.80 and an anticipated effect size of d= 0.8 (Soper, 2009).

This was a short intervention study (8 or 12 weeks). It remains unknown whether (other) outcomes might have been obtained with a longer duration of RT. It is also not clear how persistent the improvements will be, as this was beyond the scope of this study. Future research could follow-up the study participants to evaluate the ongoing enduring effects of RT. Furthermore, it remains unknown whether RT is suitable for adults above the age of 65 years. The age limit of the RT intervention was 18-65 years. Trends in physical activity have consistently shown that activity levels progressively decrease with age. The prevalence of inactivity is highest among adults aged 65 years or older (Schutzer and Graves, 2004). In addition, running has a high absolute number of injuries, a high risk of injury and a high level of injury severity, among male and female sports participants in comparison with other sports in the Netherlands (Van Mechelen et al., 2009). Elderly might be hesitant and not willing to exercise and might perceive running as a high injury prone activity. This could be a barrier for elderly to choose for RT as treatment to tackle their anxiety and/or depressive disorder. However, RT is mostly given by running therapists, who are conscious of the limits of participants' skills and competence and the factors training and coaching, which all are important factors to prevent sport injuries (Consument & Veiligheid, 2009). In addition, participants in this study did not have any sport injuries during or after the RT intervention and sport injuries were not mentioned as reason to withdrawn the study. Future research could identify if elderly face resistance or barriers to use exercise to tackle their anxiety and/or depressive symptoms and which form of exercise they prefer, since research findings have shown that hiking – a less injury prone sport – can also reduce anxiety and/or depressive symptoms (e.g. Lee and Buchner, 2008) as well as anaerobic forms of exercise (Stathopoulou et al. 2006). What also remains to be investigated is whether conventional therapies, such as cognitive behavior therapy, might further decrease the anxiety and/or depressive symptoms and whether that might serve as a second step in treatment delivery to those who do not succeed with this lowest-threshold intervention.

Other directions for research involve the potential of RT to give preliminary help to people who are currently wait-listed for more intensive treatments. This efficiency gain could also benefit patients who still clearly need face-to-face therapeutic contact. In this regard, the cost-effectiveness of RT needs to be evaluated in terms of the socio-economic costs consequences in the society and health gains in terms of physical and role functioning, bed days, work days, impairment at work, use of health services and in terms of the maintenance of health gains over time.

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APPENDICES

Appendix 1: Reflection of researcher as running therapist

Appendix 2: Leaflet for recruitment participants

Appendix 3: Informed consent for participants: Running Therapy intervention

Appendix 4: Scientific protocol for running therapists

Appendix 5: Informed consent for participants: Rationales for participation in Running Therapy

Appendix 6: SPSS output Paired Samples T-Test

Appendix 1: Reflection of researcher as running therapist

My experiences with Running Therapy started at the beginning of February 2009. In that period I attended the lecture “Running Therapy”, which was organized by “The Running Centre” in Horst, the Netherlands (11 February, 2009). Attendance of that meeting was considered important to become familiar with the concept of Running Therapy and to create a network of people that have an interest in Running Therapy.

At the end of March 2009, I observed the first session of the RT intervention, which was supervised by physiotherapist and running therapist Simon van Woerkom. Twice a week – on Tuesday and Thursday – the participants and the RT intervention group met at from 11:00 till 12:00 o’clock in Health Centre “De Kroonsteen” in Malden. The group of seven participants was quite diverse: men and woman, old and young, with and without experiences in running. Each participant had the possibility to train on his own level within the group. After a few observations, Simon offered me the opportunity to follow the post HBO-course “Running Therapy” and at the beginning of March 2009 I obtained a certificate to supervise Running Therapy sessions myself. From that time on, I supervised the RT group sessions in Malden together with Simon.

I studied the RT group in Malden for about half a year and observed the development of each participant every week. For some participants the development went with ups and down, though “there was some development”. To provide an impression of such a development, I would like to give an example of a depressed woman, who had my attention from the beginning. Her decision to start with RT was one step forward to overcome the isolated life she lived. When we first met, she appears to be shy, uncertain and sequestered. She followed the instructions, but I did not observe any interaction with the other participants. Gradually this attitude changed: enjoyment of the social aspects of running became more salient. Step by step this woman gained more self-confidence and her cardiovascular endurance improved. In September, Simon and I suggested her to participate in the Bridge to Bridge Run in Nijmegen, the Netherlands, as final activity of the RT. This woman was uncertain about her performance, since she had to run for 6.8 kilometers, which she had never done before. She severely hesitated in participating in this event. Nevertheless, her family, the participants of the RT group, and I motivated her to participate. Finally she decided to participate in the Bridge to Bridge Run. With perseverance, motivation and the ongoing social support, this woman finished with a wonderful smile. She crossed a boarder and learned that she has more power then she had ever thought.

Appendix 2: Leaflet for recruitment participants

GEZOCHT: mannen en vrouwen tussen 18 en 65 jaar met depressieve en/of angstklachten

Voor een wetenschappelijk onderzoek naar de effecten van runningtherapie ter behandeling van depressieve -en angstklachten worden er mannen en vrouwen tussen de 18 en 65 jaar gezocht die:

- Deeltijd- of ambulant patiënt zijn van De Gelderse Roos GGZ in Arnhem, Ede, Lunteren, Tiel of Wolfheze;
- Bereid zijn om gedurende een periode van 8 tot 12 weken een Runningtherapie Programma te volgen onder begeleiding van een runningtherapeut;
- Bereid zijn 1 keer per week zelfstandig een runningtherapie sessie uit te voeren. Duur en intensiteit van de runningtherapie sessie vindt in overleg met de runningtherapeut plaats;
- Bereid zijn om voor het onderzoek enkele vragenlijsten in te vullen. (Het invullen van de vragenlijsten neemt in totaal circa 30 minuten in beslag).

Doel onderzoek

Het onderzoeken van het effect van runningtherapie op de ernst van angst- en depressieve klachten. Dit, om bewijs te leveren voor de potentie van runningtherapie als complementaire behandelingsvorm voor angststoornissen en depressie. Verder heeft dit onderzoek het doel om de redenen van patiënten, om al dan niet aan het Runningtherapie Programma te participeren, in kaart te brengen.

Periode onderzoek

Februari-Mei 2009.

Meedoen of meer weten?

Bel met (telefoonnummer van desbetreffende runningtherapeut) tussen 9:00 en 17:00 uur.
U kunt tevens een e-mail sturen naar (e-mailadres van desbetreffende runningtherapeut)

Appendix 3: Informed consent for participants of Running Therapy intervention

Beste heer/mevrouw,

Om te onderzoeken of runningtherapie als complementaire behandelingsvorm voor angststoornissen en/of depressie kan worden ingezet, willen wij weten wat het effect is van runningtherapie op de ernst van angst- en depressieve klachten. Dit is belangrijk om bewijs te leveren voor de potentie van runningtherapie als behandelingsvorm. De meerwaarde van het toevoegen van runningtherapie aan andere behandelinterventies is nauwelijks onderzocht, en dus meestal niet bewezen. Wij willen u daarom uitnodigen om deel te aan dit onderzoek door enkele vragenlijsten vóór en ná de runningtherapie interventie in te vullen.

De opdrachtgevers van dit onderzoek zijn fysiotherapiepraktijk “Fysiotherapie & Sport van Woerkom” en Wageningen Universiteit. De onderzoekers zijn psychiater Bram Bakker en Carmen Voogt, Masterstudente Public Health and Society aan de Wageningen Universiteit.

Aangezien het een onderzoek is, is het niet mogelijk om iedereen met angst en/of depressieve klachten uit te nodigen. Daarom worden er slechts enkele GGZ-instellingen en fysiotherapiepraktijken in Gelderland geselecteerd om deel te nemen aan dit onderzoek.

Het onderzoek is goedgekeurd door de opdrachtgevers “Fysiotherapie & Sport van Woerkom” en Wageningen Universiteit. Er wordt zeer zorgvuldig met uw gegevens omgegaan. De gegevens die wij verzamelen worden alleen voor dit onderzoek gebruikt. Uw naam verschijnt nooit in een rapport of artikel. We doen geen uitspraken over één individu, wel over groepen (bijvoorbeeld: 45-jarige met angstklachten). De onderzoekers van dit onderzoek staan garant voor de vertrouwelijke behandeling van alle informatie.

Wij vertrouwen erop u hiermee voorlopig voldoende geïnformeerd te hebben. Aarzel niet om bij vragen of problemen contact op te nemen met de onderzoekers.

Met vriendelijke groet,

Bram Bakker, M.D., Ph.D., eerste onderzoeker	brambakker@planet.nl
Carmen Voogt, MSc, tweede onderzoeker	carmen.voogt@wur.nl
Simon van Woerkom, opdrachtgever	info@runningtherapie.nl

TOESTEMMINGSVERKLARING ("INFORMED CONSENT")

voor medewerking aan het wetenschappelijk onderzoek:

Running Therapy as complementary treatment of anxiety and depressive disorder 2009

Het effect van runningtherapie op de ernst van angst- en depressieve klachten

Doel onderzoek

Het onderzoeken van het effect van runningtherapie op de ernst van angst- en depressieve klachten. Dit, om bewijs te leveren voor de potentie van runningtherapie als complementaire behandelingsvorm voor angststoornissen en depressie. Verder heeft dit onderzoek het doel om de redenen van enkele deelnemers, om al dan niet aan runningtherapie deel te nemen, in kaart te brengen.

Beschrijving onderzoeksprocedure

De runningtherapie interventie duurt 8 tot 12 weken. Dit is afhankelijk van het aantal trainingssessies per week. Er vinden maximaal twee runningtherapiesessies per week individueel of in groepsverband plaats, onder begeleiding van een runningtherapeut van De Gelderse Roos. Als onderdeel van de therapie dient u één keer per week zelfstandig een runningtherapiesessie af te werken. De duur en intensiteit van de trainingssessies vindt in overleg met de runningtherapeut plaats. In totaal worden er 24 trainingssessies uitgevoerd, waarvan 16 onder begeleiding van een runningtherapeut en 8 zelfstandig. Gedurende het onderzoek zullen er enkele meetmomenten plaatsvinden: één voor de aanvang en één na de beëindiging van de runningtherapie interventie. De volgende metingen worden in week 1 en in week 8 respectievelijk week 12 uitgevoerd:

Symptom Checklist-90-Revised (SCL-90-R)

Om een beeld te krijgen van het beloop van uw klachten gedurende 8 respectievelijk 12 weken, wordt u gevraagd de SCL-90-R in te vullen. De SCL-90-R is een klachtenlijst gebaseerd op zelfbeoordeling door u. De afname neemt ongeveer 15 minuten in beslag.

De deelnemer:

1. Ik heb de bovenstaande schriftelijke informatie goed gelezen en begrijp wat het onderzoek en de metingen inhouden.
2. Ik ben naar tevredenheid over het onderzoek geïnformeerd.
3. Ik ben in de gelegenheid gesteld om vragen over het onderzoek te stellen en mijn vragen zijn naar tevredenheid beantwoord.
4. Ik heb goed over deelname aan het onderzoek kunnen nadenken en ik neem deel uit vrije wil.
5. Ik heb het recht mijn toestemming op ieder moment weer in te trekken zonder dat ik daarvoor een reden behoef op te geven.
6. Ik geef toestemming voor het anoniem gebruik van mijn gegevens voor wetenschappelijk onderzoek en verslaglegging. Alle gegevens zullen anoniem verwerkt worden.

Ik stem toe met deelname aan het onderzoek.

Naam deelnemer: **Handtekening:** **Datum:**

Ondergetekenden verklaren dat de hierboven genoemde persoon schriftelijk over het bovenvermelde onderzoek is geïnformeerd. Hij/zij verklaart tevens dat een voortijdige beëindiging van de deelname door bovengenoemde persoon, van geen enkele invloed zal zijn op de zorg die hem of haar toekomt.

Namen onderzoekers **Handtekening:** **Datum:**

Bram Bakker, M.D., Ph.D.

Carmen Voogt, MSc

Simon van Woerkom

** Dit formulier is bestemd voor onderzoek met personen van 18 jaar en ouder die wilsbekwaam zijn. Bij dit soort onderzoek moet door de betrokkenen zelf toestemming worden verleend.*

Appendix 4: Scientific protocol for running therapists

WETENSCHAPSPROTOCOL VOOR RUNNINGTHERAPEUTEN

voor medewerking aan het wetenschappelijk onderzoek:

Running Therapy as complementary treatment of anxiety and depressive disorder 2009

Het effect van runningtherapie op de ernst van angst- en depressieve klachten

Doel onderzoek

Het onderzoeken van het effect van runningtherapie op de ernst van angst- en depressieve klachten. Dit, om bewijs te leveren voor de potentie van runningtherapie als complementaire behandelingsvorm voor angststoornissen en depressie. Verder heeft dit onderzoek het doel om de redenen van enkele deelnemers, om al dan niet aan runningtherapie deel te nemen, in kaart te brengen.

Algemene opmerkingen

Doelgroep

- De deelnemers van het onderzoek zijn mannen en vrouwen tussen de 18 en 65 jaar met angst en/of depressieve klachten en die: 1) geen andere psychische stoornissen hebben anders dan angst- en/of stemmingsstoornissen; 2) geen contra-indicaties voor “running” hebben en 3) niet deelnemen aan andere vormen van aerobe oefeningen.

Runningtherapie Interventie

- De duur van de runningtherapie interventie van dit onderzoek bedraagt in totaal 8 tot 12 weken.
- Er wordt aanbevolen om gedurende 8 weken een trainingsfrequentie van 3 keer per week uit te voeren, waarvan 2 onder begeleiding van een runningtherapeut en 1 zelfstandig door de deelnemer. Op deze manier worden er gedurende 8 weken in totaal 24 trainingssessies uitgevoerd, waarvan 16 onder begeleiding en 8 zelfstandig. Indien de trainingsfrequentie van 3 keer per week niet haalbaar is, wordt er aanbevolen om gedurende 12 weken 2 trainingsessies per week uit te voeren, waarvan 1 onder begeleiding van een runningtherapeut en 1 zelfstandig door de deelnemer.

  Het gaat er dus om dat er in totaal 24 trainingssessies worden uitgevoerd, gedurende 8 tot 12 weken.
- Er wordt aanbevolen om een lage tot gemiddelde trainingsintensiteit te behouden, wat neer komt op circa 70 tot 80 procent van de maximale hartslagfrequentie.
- De runningtherapie interventie wordt individueel of in groepsverband (2-8 personen) uitgevoerd, daar uit onderzoek is gebleken dat er geen verschil in effectiviteit tussen trainen in een groep of alleen is waargenomen (Blumenthal et al., 2007).
- De runningtherapiesessie duurt minimaal 60 minuten en maximaal 90 minuten, inclusief warming-up en cooling-down.
- Er wordt aanbevolen om de deelnemer te stimuleren om zelfstandig één keer per week dezelfde trainingsessie af te leggen als de gegeven trainingssessie van de runningtherapeut in de betreffende week.

Metingen

- De metingen van het onderzoek vinden plaats door de afname van enkele vragenlijsten.
- De vragenlijsten worden individueel door de deelnemer met de pen-en-papier methode ingevuld.
- Er wordt vertrouwelijk met de gegevens van de ingevulde vragenlijsten van de deelnemers omgegaan. Dit houdt in dat de ingevulde vragenlijsten worden opgehaald en direct in de toegevoegde blanco envelop worden gestopt, zonder inzage van de runningtherapeut, zodat de gegevens anoniem verwerkt kunnen worden.

Afname Symptom Checklist-90-Revised (SCL-90-R)

- De SCL-90-R wordt afgenomen om een beeld te krijgen van het beloop van de angst en depressieve klachten gedurende 8 tot 12 weken. De SCL-90-R is een Multi-dimensionele klachtenlijst gebaseerd op zelfbeoordeling door de onderzochte (Arrindell en Ettema, 1986).
- De SCL-90-R wordt in totaal **twee keer** afgenomen:
  Afname 1: tijdens de intakefase. Dit betekent vóór de eerste trainingssessie in week 1.
  Afname 2: 3 tot 5 dagen ná de laatste (24^{e}) trainingssessie in week 8 respectievelijk week 12.
- De afname van de SCL-90-R neemt per keer ongeveer 15 minuten in beslag.

Benodigdheden

- Klachtenlijst Symptom Checklist-90-Revised
- Pen

Werkwijze

Week 1: 1e Afname SCL-90-R

- Deel de SCL-90-R inclusief pen aan de deelnemer uit ná de individuele kennismaking, de beoordeling van de verwijzing en het ondertekenen van toestemmingsverklaring (“informed consent”) gedurende de intakefase in week 1.
- Laat de deelnemer op een rustige plek plaatsnemen om de SCL-90-R in te vullen.
- Verzamel de SCL-90-R, nadat de deelnemer hem heeft ingevuld, en stop hem direct, zonder inzage, in de toegevoegde blanco envelop.
- Stuur de blanco envelop met de ingevulde SCL-90-R maximaal drie dagen na de afname op naar onderstaand contactadres.

Week 1-8 respectievelijk week 1-12: Uitvoering runningtherapie interventie

Week 8: 2^{e} Afname SCL-90-R

- Deel voor de tweede keer de SCL-90-R – inclusief pen – aan de deelnemers uit, drie tot vijf dagen na de laatste (24^{e}) runningtherapiesessie in week 8 of week 12.
- Laat de deelnemer op een rustige plek plaatsnemen om de SCL-90-R in te vullen.
- Verzamel de SCL-90-R, nadat de deelnemer hem heeft ingevuld, en stop hem direct, zonder inzage, in de toegevoegde blanco envelop.
- Stuur de blanco envelop met de ingevulde SCL-90-R maximaal drie dagen na de afname op naar onderstaand contactadres.

De vragenlijst(en) mogen zelfstandig afgenomen worden door:

- Psycholoog is bevoegd
- Psychiater is bevoegd
- Runningtherapeut(e) is bevoegd onder auspiciën van psychiater Bram Bakker

Ik stem toe voor medewerking aan het onderzoek.

Naam runningtherapeut(e): **Handtekening:** **Datum:**

Namen onderzoekers: **Handtekening:** **Datum:**

Bram Bakker, M.D., Ph.D.

Carmen Voogt, MSc

Simon van Woerkom

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Voor een overzicht van het aantal te verrichten metingen voor het onderzoek, zie onderstaande tabel.

Tabel 1: Data collectie schema gedurende runningtherapie interventie van 8 weken

WEEK → METING↓	**AFNAME IN TIJD**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Maximale duur metingen intakefase	***30 min.***	***x***							
Kennismaking	5	*x*							
Beoordeling verwijzing	5	*x*							
Ondertekenen toestemmingsverklaring	5	*x*							
SCL-90-R (pre-test: T1)	15	*x*							
Maximale duur interventie (X) op basis van 2 sessies p/w onder begeleiding van runningtherapeut en 1 sessie facultatief door deelnemer	***36 uur***	***x***	***x***	***x***	***x***	***x***	***x***	***x***	***x***
Duur trainingssessie per keer	60-90	*x*	*x*	*x*	*x*	*x*	*x*	*x*	*x*
Maximale duur her- metingen	***15 min.***								***x***
SCL-90-R (post-test: T2)	15								*x*
MAXIMALE DUUR ↓	**Circa 37 uur**								

Appendix 5: Informed consent for participants: Rationales for participation in Running Therapy

TOESTEMMINGSVERKLARING ("INFORMED CONSENT")

voor medewerking aan een semi-gestructueerd interview voor het wetenschappelijk onderzoek:

Running Therapy as complementary treatment of anxiety and depressive disorder 2009

Het effect van runningtherapie op de ernst van angst- en depressieve klachten

Beste heer/mevrouw,

Ik wil u graag bedanken voor uw tijd om mij vandaag te ontmoeten. Mijn naam is Carmen Voogt en ik zou graag met u over uw beweegredenen voor deelname aan runningtherapie willen praten.

Het interview duurt maximaal een half uur. Ik zou graag het interview op tape willen opnemen om de kans te verkleinen dat ik opmerkingen vergeet. Ik wil u verzoeken rustig en duidelijk te praten, zodat u goed verstaanbaar bent op de tape. Gedurende het interview zal ik enkele notities maken.

Er wordt vertrouwelijk en zeer zorgvuldig met uw gegevens omgegaan. De gegevens die ik verzamel worden alleen voor dit onderzoek gebruikt. Uw naam verschijnt nooit in een rapport of artikel. U hoeft niet te antwoorden op vragen waarop u geen antwoord wilt geven en u kunt het interview stoppen op ieder moment.

Zijn er nog vragen of onduidelijkheden die ik kan beantwoorden?

Bent u bereidt deel te nemen aan dit interview?

Naam geïnterviewde:	**Naam onderzoeker:** Carmen Voogt, MSc
Handtekening:	**Handtekening:**
Datum:	**Datum:**

Dit formulier is bestemd voor onderzoek met personen van 18 jaar en ouder die wilsbekwaam zijn. Bij dit soort onderzoek moet door de betrokkenen zelf toestemming worden verleend.

Appendix 6: SPSS output Paired Samples T-Test & Wilcoxon Test for Two Related Samples

1) SPSS output Paired Samples T-Test →

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	angstT1	20.88	8	8.887	3.142
	angstT2	16.88	8	7.357	2.601
Pair 2	depressieT1	38.38	8	18.408	6.508
	depressieT2	29.88	8	14.759	5.218

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	angstT1 & angstT2	8	.948	.000
Pair 2	depressieT1 & depressieT2	8	.867	.005

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	angstT1 - angstT2	4.000	3.024	1.069	1.472	6.528	3.742	7	.007
Pair 2	depressieT1 - depressieT2	8.500	9.258	3.273	.760	16.240	2.597	7	.036

T-values: 3.742 (anxiety) and 2.597 (depression)

P-values: .007 (anxiety) and .036 (depression)

Effect sizes d= 1.32 (anxiety) & d= .92 (depression) (Paired Samples Test: mean/std.deviation):

2) SPSS output Non-parametric Wilcoxon Test for Two Related Samples →

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
catangstT1	8	5,75	1,488	3	7
catdepressieT1	8	5,63	1,685	3	7
catangstT2	8	5,00	1,927	3	7
catdepressieT2	8	5,00	1,414	3	7

Ranks

		N	Mean Rank	Sum of Ranks
catangstT2 - catangstT1	Negative Ranks	3[a]	2,00	6,00
	Positive Ranks	0[b]	,00	,00
	Ties	5[c]		
	Total	8		
catdepressieT2 - catdepressieT1	Negative Ranks	5[d]	3,10	15,50
	Positive Ranks	1[e]	5,50	5,50
	Ties	2[f]		
	Total	8		

a. catangstT2 < catangstT1

b. catangstT2 > catangstT1

c. catangstT2 = catangstT1

d. catdepressieT2 < catdepressieT1

e. catdepressieT2 > catdepressieT1

f. catdepressieT2 = catdepressieT1

Test Statistics[b]

	catangstT2 - catangstT1	catdepressieT2 - catdepressieT1
Z	-1,604[a]	-1,063[a]
Asymp. Sig. (2-tailed)	,109	,288

a. Based on positive ranks.

b. Wilcoxon Signed Ranks Test

Z-values: -1.604 (anxiety) and -1.063 (depression)

P-values: .109 (anxiety) and .288 (depression)

Effect sizes: r= .40 (anxiety) and r= .27 (depression) (Test statistics: Z/ / √ (2 x 8 observations)