FROM THE DEPARTMENT OF NEUROBIOLOGY, CARE SCIENCES AND SOCIETY

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PRIMARY CARE PATIENTS WITH COMMON MENTAL DISORDERS
QUALITY OF LIFE, SICK LEAVE AND EFFECTS OF GROUP THERAPY

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PRIMARY CARE FOR PATIENTS WITH COMMON MENTAL DISORDERS
QUALITY OF LIFE, SICK LEAVE AND EFFECTS OF GROUP THERAPY

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To all my co-workers at Gustavsberg and Djurö Primary Care Centers who have made this possible.
ABSTRACT

Background: Depression, Anxiety and Stress-Related Disorders, Common Mental Disorders (CMDs) are common among patients in primary health care, with many left untreated or even undiagnosed. CMDs are associated with high societal costs, and are the main cause of increasing Sick Leave among patients in primary health care. Effective treatments are not widely available in primary care. In addition, the associations between Clinical and Treatment-Related Factors, Patient Variables, Sick Leave and the Quality of Life are not well investigated. Research is needed in order to identify factors related to Health Outcomes, as well as to develop treatments that are well suited for primary care settings.

Aims: The objective of the present thesis was to investigate the following: (a) The effects of two different group interventions for CMD in a primary care setting (Paper I), (b) the effects on active treatments on Sick Leave in a primary care setting (Paper II), (c) patient characteristics and their associations with the Quality of Life (QoL) (Paper III) and (d) how patient variables compared to treatments can predict QoL one year after treatment (Paper IV).

Methods: One large-scale randomized controlled trial (RCT) was conducted. In Paper I, a group intervention with a Transdiagnostic Manual based on Cognitive Behavioral Treatment(CBT) + Care as Usual(CAU) (n= 80) was compared to group with Multimodal Intervention(MMI) led by assistant nurses + CAU (n= 84) and CAU (n=81). Paper II compared treatment effects of group CBT + CAU (n=45) and MMI + CAU (n=58) compared to CAU (n=61) on Sick Leave. In Paper III, associations between patient variables and QoL were examined using a linear regression model. Paper IV examined associations between patient variables, treatment effects of group CBT + CAU, MMI + CAU or CAU and QoL one year after treatment, using a linear regression model. We used the Mental Component Summary (MCS) and the Physical Summary Score (PCS) of short form 36 (SF-36) to measure QoL.

Results: Study 1: the MMI + CAU group was significantly more improved than the CBT + CAU and CAU groups. The CBT + CAU group was significantly more improved than the CAU group. Study 2: The mean number of Sick Leave days decreased after randomization and the CBT and MMI interventions did not result in lower odds for sick listing compared with CAU. Study 3: Depressive Disorders and symptoms had the strongest effects on MCS. Study IV: background factors such as being employed, being born outside Sweden as well as having a Personality Disorder (PD) were strong predictors for QoL one year after treatment. The strongest positive predictor of MCS one year after treatment was the Group Treatment MMI.

Conclusions: Transdiagnostic Group Treatment led by assistant nurses in a primary care setting can be effective for patients with CMD. Reduction in Psychological Symptoms and increased Well-Being did not seem to have effect on Sick Leave. For primary care patients with mild to moderate Mental Illness, Mood Disorder and Depressive Symptoms were the strongest factors associated with negative influence on MCS. Effective Treatment and Being Employed had the strongest positive impact on QoL one year after treatment. PD had the strongest negative impact together with Being Born Outside Sweden. Increased priority for treatment of CMD in primary care is of great importance.

Key words: Common Mental Disorders (CMDs), Primary Care, Transdiagnostic Group Treatments, Personality Disorder, Personality Traits, Predictors, Quality of Life, Sick Leave
LIST OF SCIENTIFIC PAPERS


# CONTENTS

1. CONTENTS..........................................................................................................................................................5
2. LIST OF ABBREVIATIONS .................................................................................................................................6
3. INTRODUCTION ..................................................................................................................................................8
4. BACKGROUND ....................................................................................................................................................9
   4.1 COMMON MENTAL DISORDERS (CMDs) IN PRIMARY CARE ......................................................................9
       4.1.1 Anxiety and Depression are Common Mental Disorders in Primary Care ..............................................10
       4.1.2 Stress-Related Disorders ....................................................................................................................12
   4.2 CMD in primary care since 1995 in Stockholm County .................................................................................15
   4.3 PSYCHOLOGICAL TREATMENTS: CBT, IPT, and PDT ...............................................................................16
   4.4 PERSONALITY TRAITS .............................................................................................................................18
   4.5 PERSONALITY DISORDER ........................................................................................................................19
   4.6 SICK LEAVE .............................................................................................................................................22
   4.7 QUALITY OF LIFE ...................................................................................................................................24
5. AIMS OF THE PRESENT THESIS .....................................................................................................................26
   5.1 PAPERS I and II ...........................................................................................................................................26
   5.2 PAPER III ...................................................................................................................................................26
   5.3 PAPER IV ...................................................................................................................................................26
6. ETHICS ..............................................................................................................................................................27
7. STATISTICS .........................................................................................................................................................28
   7.1 Paper I .......................................................................................................................................................28
   7.2 Paper II .......................................................................................................................................................28
   7.3 Paper III .......................................................................................................................................................28
   7.4 Paper IV .......................................................................................................................................................28
8. MATERIAL AND METHODS .............................................................................................................................30
9. RESULTS .............................................................................................................................................................34
   9.1 PAPER I-II ..................................................................................................................................................35
   9.2 Papers III-VI ................................................................................................................................................37
10. DISCUSSION ......................................................................................................................................................41
   10.1 METHODOLOGICAL CONSIDERATIONS .................................................................................................41
       10.1.1 Paper I ...............................................................................................................................................41
       10.1.2 Paper II ...............................................................................................................................................42
       10.1.3 Papers III and IV ...............................................................................................................................42
   10.2 GENERAL DISCUSSION AND MAIN FINDINGS ....................................................................................43
       10.2.1 Group treatments ...............................................................................................................................43
       10.2.2 Sick Leave ..........................................................................................................................................45
       10.2.3 Factors associated with and predicting QoL ....................................................................................46
11. CONCLUSIONS ..................................................................................................................................................48
12. IMPLICATIONS AND FUTURE PERSPECTIVES ............................................................................................49
13. SUMMARY IN SWEDISH ................................................................................................................................50
14. LEARNING AND OUTCOMES ..........................................................................................................................52
15. ACKNOWLEDGMENTS ..................................................................................................................................53
16. REFERENCES .....................................................................................................................................................54
# 2 LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AUDIT</td>
<td>Alcohol Use Disorders Identification Test</td>
</tr>
<tr>
<td>BMI</td>
<td>Body Mass Index</td>
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<tr>
<td>BP</td>
<td>Bodily Pain</td>
</tr>
<tr>
<td>CAU</td>
<td>Care as Usual</td>
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<tr>
<td>CBT</td>
<td>Cognitive Behavioral Therapy</td>
</tr>
<tr>
<td>CMD</td>
<td>Common Mental Disorder</td>
</tr>
<tr>
<td>CPRS</td>
<td>Comprehensive Psychopathological Rating Scale</td>
</tr>
<tr>
<td>CPRS-S-A</td>
<td>Comprehensive Psychopathological Rating Scale for Affective Syndromes</td>
</tr>
<tr>
<td>DSM-IV</td>
<td>Diagnostic and Statistical Manual of Mental Disorders, 4th Edition</td>
</tr>
<tr>
<td>GHP</td>
<td>General Health Perceptions</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>HP5i</td>
<td>Health-related Personality inventory</td>
</tr>
<tr>
<td>HRQoL</td>
<td>Health-related Quality of Life</td>
</tr>
<tr>
<td>IPT</td>
<td>Interpersonal Psychotherapy</td>
</tr>
<tr>
<td>M</td>
<td>Mean</td>
</tr>
<tr>
<td>MADRS-S</td>
<td>Montgomery Åsberg Depression Rating Scale Self-report</td>
</tr>
<tr>
<td>MCS</td>
<td>Mental Component Summary</td>
</tr>
<tr>
<td>MD</td>
<td>Mental Disorder</td>
</tr>
<tr>
<td>MH</td>
<td>Mental health</td>
</tr>
<tr>
<td>MMI</td>
<td>Multimodal intervention</td>
</tr>
<tr>
<td>MPA</td>
<td>Medical Products Agency</td>
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<tr>
<td>NBHW</td>
<td>National Board of Health and Welfare</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
</tr>
<tr>
<td>OCD</td>
<td>Obsessive Compulsive Disorder</td>
</tr>
<tr>
<td>OR</td>
<td>Odds Ratio</td>
</tr>
<tr>
<td>PC</td>
<td>Primary Care</td>
</tr>
<tr>
<td>PCS</td>
<td>Physical Component Summary Scale</td>
</tr>
<tr>
<td>PD</td>
<td>Personal Disorder</td>
</tr>
<tr>
<td>PD-NOS</td>
<td>Personal Disorder – Not Otherwise Specified</td>
</tr>
<tr>
<td>PDT</td>
<td>Psychodynamic therapy</td>
</tr>
<tr>
<td>PD-TS</td>
<td>Personal Disorder – Trait Specified</td>
</tr>
<tr>
<td>PFS</td>
<td>Physical Functioning Scale</td>
</tr>
<tr>
<td>PSS</td>
<td>Perceived Stress Scale</td>
</tr>
<tr>
<td>QoL</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>QOLI</td>
<td>Quality of Life Inventory</td>
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</tbody>
</table>
3 INTRODUCTION

By the time when the research plan underlying this thesis was created in 2002, the Gustavsberg Primary Care Center was serving 28,000 inhabitants and was one of the largest primary care centers in Sweden. As a manager of the care center since 1997, I had noticed that one of the greatest needs was to improve the care for patients with mental illness. Primary care in 2002 was focused to a large extent on patients with diseases that cause early death, such as cardiovascular disease and diabetes. There was clearly much less focus on Common Mental Disorders, such as Depression and Anxiety. In the early 1990s, General Practitioners (GPs) were the sole caregivers in primary care for patients with Common Mental Disorders. Two events around this time, the introduction of SSRIs, (Selective Serotonin Reuptake Inhibitors) as anti depressive medication in primary care, as well as fundings by the Stockholm County Council to employ counselors, improved the care for some patients. In 2002, access to psychological treatment at our Primary Care Center was almost non-existent, although one counselor with basic training in psychotherapy had been employed to give care to 28,000 inhabitants together with 15 general practitioners. Even though the prescriptions for anti-depressive medications increased every year, notings of Common Mental Disorders in the medical records were sparse possibly partly in order not to stigmatize the patients. Thus, there was a great need to make Common Mental Disorders visible within primary care and to develop and evaluate treatment protocols with the goal of improving the care for patients with Common Mental Disorders. A pilot treatment project was started in 2002 at the Gustavsberg Primary Care Center and was followed by the four studies comprising the present thesis.

Gustavsberg, May, 2017
4 BACKGROUND

4.1 COMMON MENTAL DISORDERS (CMDs) IN PRIMARY CARE

CMDs stand for Common Mental Disorders. The term is used in international literature and usually includes the diagnoses Depression, Generalized Anxiety Disorder, Panic Disorder, Specific Phobias, Obsessive-Compulsive Disorder and Post-Traumatic Stress Disorder, according to the National Institute for Health and Care Excellence, NICE. CMDs in primary care usually include mild to moderate Depressive and Anxiety Disorders. Stress-Related Disorders, especially Acute Stress Disorder and Adjustment Disorder, are important conditions. In Sweden, the diagnosis “Exhaustion Syndrome”, described as a Prolonged Adjustment Disorder and recognized and accepted by the Swedish National Board of Health and Welfare (NBHW) since 2005, is handled in primary care, at least if the condition is not too severe. The detection and treatment of Alcohol Dependency is also a task for primary care and so is the case for Insomnia.

Diagnostic and Statistical Manual of Mental Disorders, is a handbook and a guide in the diagnosis of Mental Disorders. It is published by the American Psychiatric Association (APA) and the first version was first published in 1952. The latest version of DSM was published in 2013 (DSM-5). In the present thesis, we used DSM IV. Somatic Syndrome Disorder has replaced Somatization Disorder and Undifferentiated Somatoform Disorder and Illness Anxiety Disorder has replaced Hypochondria in DSM-5. These conditions are also common in primary care.

Obsessive-Compulsive Disorder (OCD) is described in DSM-5 as a separate diagnostic group and not, as previously, as a part of Anxiety Disorders. OCD is now described together with Body Dysmorphic Disorder, Hoarding Disorder, Trichotillomania (Hair-Pulling Disorder) and Excoriation (Skin-Picking) Disorder. This group of disorders normally belongs to Specialist Psychiatric Care. The same is true for Psychotic Disorders and Bipolar Disorders. Table 1 shows Common Mental Disorders according to DSM-5 and their corresponding to ICD-10 codes (International Classification Diseases).
Table 1. Common Mental Disorders in primary care. DSM-5 and corresponding ICD-10 codes.

<table>
<thead>
<tr>
<th>Common Mental Disorders in primary care</th>
<th>ICD-10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sleep-Wake Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Insomnia Disorder</td>
<td>G47.00</td>
</tr>
<tr>
<td><strong>Substance-Related and Addictive Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Alcohol Use Disorder</td>
<td>F10.2</td>
</tr>
<tr>
<td><strong>Depressive Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Major Depressive Disorder, single episode</td>
<td>F32.0-F32.9</td>
</tr>
<tr>
<td>Mild</td>
<td>F32.0</td>
</tr>
<tr>
<td>Moderate</td>
<td>F32.1</td>
</tr>
<tr>
<td>Severe</td>
<td>F32.2</td>
</tr>
<tr>
<td>Major Depressive Disorder, recurring episode</td>
<td>F33.0-F33.9</td>
</tr>
<tr>
<td>Persistent Depressive Disorder (Dysthymia)</td>
<td>F34.1</td>
</tr>
<tr>
<td><strong>Anxiety Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Agoraphobia</td>
<td>F40.00</td>
</tr>
<tr>
<td>Social Anxiety Disorder</td>
<td>F40.10</td>
</tr>
<tr>
<td>Specific Phobia</td>
<td>F40.218-F40.298</td>
</tr>
<tr>
<td>Panic Disorder</td>
<td>F41.0</td>
</tr>
<tr>
<td>Generalized Anxiety Disorder</td>
<td>F41.1</td>
</tr>
<tr>
<td><strong>Obsessive-Compulsive Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Obsessive-Compulsive Disorder</td>
<td>F42.0-F42.9</td>
</tr>
<tr>
<td><strong>Trauma- and Stressor-Related Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Acute Stress Disorder</td>
<td>F43.0</td>
</tr>
<tr>
<td>Adjustment Disorders, unspecified</td>
<td>F43.20</td>
</tr>
<tr>
<td><strong>Somatic Symptom Disorder</strong></td>
<td></td>
</tr>
<tr>
<td>F43.8A Exhaustion syndrome</td>
<td></td>
</tr>
<tr>
<td>Somatic Symptom Disorder</td>
<td>F451</td>
</tr>
<tr>
<td>Illness Anxiety Disorder</td>
<td>F452</td>
</tr>
</tbody>
</table>

4.1.1 Anxiety and Depression are Common Mental Disorders in Primary Care

WHO predicts that Depression will be the diagnosis that contributes most to the burden of disease by the year 2030 [1]. Anxiety and Depressive Disorders are associated with a low Quality of Life (QoL) and are often left untreated in primary care [2-9]. Most of the Sick Leave due to Mental Illness in Sweden is caused by Anxiety, Depression and Stress-Related Disorders [10-12]. There is a general agreement that there are Evidence-Based Treatments available for Anxiety and Depressive Disorders [13, 14] while the situation is not so clear for Stress-Related Disorders. There is evidence for the effectiveness of both Psychotherapeutic and Pharmacological treatments for Anxiety and Depression. However, in the Stockholm County Council (SLL) area, only 3% of the patients are offered other Treatments than Pharmacological Treatment [4].
Depression and Anxiety Disorders are common worldwide [1, 5, 15] and the association between the two disorders is high. In a Swedish postal survey in 2013 [2] 17% of the responders were experiencing either Depression (10.8%) and/or Anxiety (14.7%). Around 50% had both disorders. A low quality of life was associated with these disorders and the disorders were often untreated. In a national US survey in 2004 [6] the 12-month prevalence of Depression was 9.2% and the prevalence of Anxiety Disorders was 11.1%, which is similar to the results of the Swedish survey. The most common Anxiety Disorders were Specific Phobia (7.1%), Social Phobia (2.8%) and Generalized Anxiety Disorder (2.1%). Compared to population data, patients in primary care have, as expected, a high prevalence of Mental Disorders. In Belgium, a cross-sectional survey [15] discovered a Mental Disorder in over 40% of the primary care patients attending 86 different general practices. Mood Disorders were most frequent. In a cross-sectional study in Spain [5], a 23% rate of Mental Disorders was found among the attendees of eight different Primary Care Centers. QoL was impaired in the patients with Mental Disorders, and the impairment was most pronounced in the patients with Mood Disorders In Sweden, it has usually been estimated that around every third patient visiting primary care suffers from CMDs [16, 17].

The impairment in the Health-Related Quality of Life (HRQoL) in primary care patients with Mental Disorders is generally considered to be larger than the impairment in patients with Common Somatic Disorders [18]. The patients who suffer from Anxiety and Mood Disorders often present with physical rather than psychological symptoms [19].

**Guidelines from the National Board of Health and Welfare (NBHW) for Treatments of Depression and Anxiety from 2016**

The latest guidelines from the Swedish NBHW for Depression and Anxiety (http://www.socialstyrelsen.se/publikationer2016/2016-12-6, December, 2016) highlight the importance of early interventions. They recommend that healthcare providers offer high availability to patients with symptoms of Depression and Anxiety in order to assess the degree of severity and offer treatment at an early stage. The guidelines state that patients with a Depression or Anxiety Syndrome who do not receive correct treatment at an early stage are at higher risk for decreased functional ability, long-term illness and disease relapse, as well as a higher risk of suicide.

The recommendations suggest that these patients should be scheduled for regular follow-ups since continuity is of great importance for detecting conditions that are more serious,
improving the prognosis, and increasing compliance. It is stated that offering high availability and continuity within the health-care system demands increased resources.

According to the new guidelines, psychological interventions, preferably Cognitive Behavioral Therapy (CBT), are the main treatment for all conditions of mild to moderate Depression and Anxiety Disorders. Interpersonal Psychotherapy (IPT) is also recommended for mild and moderate cases of Depression as is, to a lower degree, Short-Term Psychodynamic Therapy (PDT).

**Medical Products Agency and Recommendations from 2016**

New strategies and recommendations for the treatment of Depression and Anxiety Disorders were published in the fall 2016 by the Medical Products Agency (MPA), and are oriented toward various combinations of treatments and social/work-related interventions (https://lakemedelsverket.se/upload/halso-och-sjukvast/behandlingsrekommendationer/Info_fran_LV_nr_6_2016_behandlingsrekommendation_webbpublicering.pdf).

The agency states that both anti-depressive pharmaceuticals and specific psychotherapy (CBT or IPT) have a proven effect and that, in many cases, the combination of the two enhances the effect. Recommendations for moderate Depression include anti-depressives and/or psychological treatment with SSRI, such as escitalopram and sertraline, as the preferred drugs. It is highlighted that, in Depression, switches within the pharmacological group may be necessary and frequent follow-ups are recommended to re-estimate the symptoms. Great emphasis is placed on lifestyle changes. OCD is treated in the same way with CBT first, with or without SSRIs, in the same ranking as for the other Anxiety Syndromes. For most cases of mild Depression, pharmaceuticals are not recommended. Physical activity is recommended for mild to moderate Depression with the optimal anti-depressive dosing schedule being 30 minutes, 3 times per week, preferably led by an instructor.

### 4.1.2 Stress-Related Disorders

Stress-Related Mental Illness is the most common reason for Sick Leave in Sweden today, and one of the most common causes of decreased work capacity [10, 12, 20].

According to DSM-5, an acute stress reaction is a short-term, strong reaction to a traumatic event and is, by definition, diagnosed between three days and one month after experiencing or learning about the event. Symptoms begin after the event and fall into five categories:
negative mood, as well as intrusive, dissociative, avoidance, and arousal symptoms. Social, Interpersonal, or Occupational Functioning can be disrupted. Extreme levels of Anxiety can disturb sleep; interfere with the ability to tend to tasks and lower energy levels. Avoidance of stimuli related to the traumatic event can cause withdrawal and nonattendance at important events.

Adjustment Disorder is a disproportionate reaction to one or more stressors in life, ranging from marital problems, and chronic illness or financial difficulties to living in a crime-ridden community or surviving a natural disaster. Developmental changes such as moving away from home, becoming a parent or retirement may also trigger emotional or behavioral symptoms that can cause significant impairments of functioning at work, in school or socially. The symptoms can last up to six months after the stressor is no longer present.

The condition Exhaustion Syndrome, recognized and accepted by the Swedish National board of Health and Welfare since 2005, is classified according to the Swedish ICD-10 as diagnosis code F438A. Since 2016, this is the most common disorder causing Sick Leave in Sweden according to the Swedish Insurance Company. The patients are usually treated in primary care for mild to moderate degrees of this condition. In 2003, the National Board of Health and Welfare in 2003 (Table 2) described the diagnosis criteria.
### Table 2. Criteria for Exhaustion Disorder. Source: The National Board of Health and Welfare.

<table>
<thead>
<tr>
<th>Criteria</th>
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<tbody>
<tr>
<td><strong>Diagnostic criteria for Exhaustion Syndrome</strong></td>
</tr>
<tr>
<td>All criteria marked in capital letters must be satisfied in order fulfill the diagnosis.</td>
</tr>
<tr>
<td><strong>A</strong></td>
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<td><strong>B</strong></td>
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<td><strong>C</strong></td>
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From a medical point of view, the etiology is summarized as a long-term exposure to stress leading to physiological changes that have a long recovery period. According to a well-known researcher on this subject, Marie Åsberg [21], the most common cause of this syndrome is regarded as an increase in work load over time without sufficient recovery time. This has been shown to often correlate with reorganizations in the work-place or a decrease in workforce. Women are affected much more often than men. The syndrome is characterized by fatigue which is not relieved by rest, cognitive problems (deficiencies in concentration, episodic memory and orientation), increased sensitivity of the senses (light, sound) and general increased sensitivity to stress. It is preceded by a longer period (by definition a minimum of 6 months) of stress. Usually a prodromal phase of physical symptoms has been present long before the syndrome is diagnosed. The acute phase that follows is often induced by a sudden increase in workload or troubles in the home situation. It is often dramatic and is referred to as “hitting the wall”. Marie Åsberg summarizes that so far, no scientific study has shown a rehabilitation model that is significantly better than any other, except models that include rehabilitation integrated with the work-place. Many patients report CBT as being helpful but does not shorten the sick leave time. Physical exercise is an essential part of rehabilitation as soon as patient is out of the acute phase.

4.2 CMD IN PRIMARY CARE SINCE 1995 IN STOCKHOLM COUNTY

Primary Care Centers in Stockholm County, approximately 180 in number, provide Primary Care to two million people. Since 1995, the Primary Care Centers in Stockholm County have been able to employ counselors/social workers with funding from the County Council. Some of the counselors had psychotherapeutic training and the general practitioners referred patients with different problems to them. No diagnostic procedure was required by the County Council, nor were assessments before and after treatment required. One, or perhaps two, counselors per 25,000 inhabitants and approximately one general practitioner per 2,000 to 3,000 inhabitants were the typical ratios. Since 2008, patients have been able to freely choose one of the 180 Primary Care Centers according to the political legislation. Around the year 2000, psychologists started to be employed. Primary Care Centers are fully paid by the County Council up to 1.9 visits to the GP per listed inhabitant, and there after there is a reduction per visit (33%). In 2008, the Primary Care Centers were fully paid, on average, for 0.1 visit to a counselor or psychologist per
year per listed inhabitant. Since then, the quotient has been slowly raised to 0.2 during 2016 and up to 0.3 since 2017.

Is an average of 0.3 visits annually per listed inhabitant enough to be able to provide evidence-based care according to the National Guidelines for Depression and Anxiety, published by the Swedish NBHW in 2016? In different studies [5, 6, 15-17], approximately 25% of the patients in primary care in Sweden have been found to have a mental problem. In a Swedish study from 2014 [4] concerning all patients in Stockholm County, 7% had received a psychiatric diagnosis, while 17% had been prescribed psychotropic drugs and only 3% had visited a counselor or psychologist during 2011.

According to a recently published report entitled “Time for Focus on Data for Common Mental Disorders in primary care, Stockholm County”, 73% of all patients in the Stockholm County Council Area with psychiatric diagnoses were given treatment in primary care and 26% of them also received treatment somewhere else during 2011-2015 [22].

4.3 PSYCHOLOGICAL TREATMENTS: CBT, IPT, AND PDT

Cognitive Behavioral Therapy - CBT

CBT is a form of psychological treatment developed from behavioral, cognitive and social psychology [23, 24]. It is research-based and the emphasis lies more on understanding and changing the patient’s current life situation than investigating the past. The treatment components target the interplay between the individual and his/her environment and the primary therapeutic goal is to help the patient develop novel and more functional ways to function, feel, think, and handle problems. Behavioral change is a primary intervention in CBT, as opposed to being a secondary effect of the treatment, as in other psychotherapeutic models.

Core CBT components include psychoeducation, exposure therapy, behavioral activation, behavioral experiments, cognitive techniques and homework assignments. Specific and measurable behavioral goals are set for each patient and one of the main aims of the therapy is to educate and empower the patient in order to increase self-efficacy. In the more recent development of CBT, components based on acceptance and mindfulness have been added to the therapeutic model.
CBT Unified Protocol

There is a large comorbidity between Common Mental Disorders [2, 5, 6, 25]. To address this situation, Dr. David Barlow, a well-known psychologist and researcher in Boston, developed a CBT-based manual for Transdiagnostic Psychological Treatment, also called Unified Protocol [25-27]. The manual has been developed for both Anxiety Disorders and Depression instead of different manuals for each diagnosis.

Patients with Anxiety Disorders experience feelings more frequently, more intensely, and more distressingly than people without these disorders. In Anxiety Disorders or Emotional Disorders, the experience of strong, uncomfortable emotions may create dysfunction in various areas of a person’s life. The strong emotions tend to be so distressing that the affected individuals might start to do things, or escape from certain situations, to avoid experiencing the intense feelings [25, 28]. According to the workbook “Unified Protocol for Transdiagnostic Treatment of Emotional Disorders” the following treatment goals are important for patients:

- Learning to be an observer instead of a victim of one’s emotional experiences
- Keeping ongoing records of one’s experiences
- Learning to observe when and where uncomfortable emotions occur
- Learning to recognize how thinking, feelings and actions can contribute to uncomfortable or distressing emotional experiences
- Learning more helpful ways of coping with emotional experiences
- Learning to record more objectively how many times certain feelings arise and the responses to those feelings (thoughts, actions and additional feelings)
- Learning to identify specific triggers of Anxiety and Depression Episodes

Interpersonal Psychotherapy - IPT

Interpersonal psychotherapy was initially developed as a treatment for major Depression. The model primarily regards the negative emotions and depressive symptoms as effects of difficult social and interpersonal stressors [29]. The focus lies on the patients’ emotions and current life situation. Interpersonal difficulties are assessed in terms of disputes, bereavements, sensitivities and role transitions. Negative patterns are identified and broken in order to achieve an improvement in interpersonal functioning and a reduction in depressive symptoms.
Short-term Psychodynamic Therapy - PDT

Psychodynamic Therapy focuses primarily on understanding the inner world of the patient, with an emphasis on the unconscious [30, 31]. Wishes, feelings, dreams and fantasies are explored. The impact of early developmental factors is important for understanding current psychopathology, even in short-term psychotherapy. The therapeutic relationship and dynamics between the therapist and the patient are also important aspects in PDT. Difficult symptoms are understood as conflicts between the conscious or unconscious needs or desires of an individual and restrictions in the environment.

4.4 PERSONALITY TRAITS

Personality has long been of interest to philosophers and scientists. Although psychologists are also interested in Personality Traits, there is less knowledge about how such traits affect public health [32].

Today, the dominant model in Personality Psychology is called The Big Five [33-36]. The Five Personality Traits are usually described as degrees of Extraversion, Neuroticism, Agreeableness, Conscientiousness, and Openness.

Personality Traits are associated with both Mental and with Physical Health and, success in one’s professional life and are linked to the quality of Interpersonal Relationships [37]. Research has also shown that there is a link between Personality and certain Mental Disorders.

Anxiety and Depression and are linked to both Neuroticism and low Extraversion [38, 39]. The links between Personality and Personality Disorders are strong and Personality Disorders have been suggested to be an extreme expression of Personality [40]. Research has shown that Personality has more influence on Subjective Well-Being than other variables such as Social Class, Marital Status, Age, and Employment [41].

There are associations between the Personality Trait High Degree of Extraversion and positive health outcomes [42]. Low Conscientiousness is related to smoking and lack of exercise [43]. There are strong associations between the Personality Dispositions and Anxiety Disorders, and Depressive Disorders, as well as Personality Disorders. Anxiety Disorders are associated with Neuroticism, and Depression is associated with Neuroticism and low Extraversion [38, 44].
4.5 PERSONALITY DISORDER

Personality Disorder (PD) is generally defined as a pattern of thinking, feeling and behaving that deviates from the expectations of the socio-cultural environment. The main characteristic of PD is difficulties in interacting with other human beings [45]. PDs are common in all medical settings and every medical practitioner will meet them frequently. In the US, 50% of patients with any Mental Disorder have a PD, which makes it one of the most common psychiatric disorders [46]. People with PD had lower Quality of Life compared to a healthy population in a Finnish population-based sample [47]. Compared to patients with serious Somatic Illness Patients with a PD have in general low QoL [48, 49]. About a quarter of patients in primary care meet the criteria and prevalence in the general population is 5 - 10% [50-52]. In Swedish survey, the prevalence of PD was 11% in the whole population [53]. Many individuals remain undiagnosed and might be treated incorrectly or in a harmful way. In the US survey, there was a positive and significant association between the PDs, Anxiety Disorders and Depression. The PDs most strongly associated with Anxiety Disorders and Depression were Avoidant and Dependent PDs and the most prevalent PD was Obsessive-Compulsive Personality Disorder (7.9%).

Common to all PDs is that the general diagnostic criteria must be met before further classification can be done. The pattern of behavior should be inflexible and prominent in various situations and circumstances. Traits should have been stable since adolescence and cause significant distress or problems in functioning. In addition, the personality pattern should not be better explained as an expression of another psychiatric illness or somatic disease, or be a direct physiological effect of a substance. The demarcation between clinical syndromes and personality syndromes is not always clear and comorbidity is very common.

In both DSM-IV and in DSM-5, 10 different PDs are described. In this thesis, we used DSM-IV. In DSM-5, the PDs are divided into three clusters and are now parts of other psychiatric diagnoses.

Cluster A: Paranoid PD, Schizoid PD, Schizotypal PD

Individuals with these disorders are “odd” and reclusive and have a very limited social network. Their limited social skills cause them to have difficulties fitting in to working life.

Cluster B: Antisocial PD, Borderline PD, Histrionic PD, Narcissistic PD

Individuals with these disorders are outgoing, often dramatic, colorful, and conflict-prone. They can have problematic relationships with other people, as well as difficulties in the
workplace because of their impulsiveness, lack of empathy, or emotional instability. There are currently a number of different psychotherapeutic treatment programs specifically geared toward borderline disorder and have shown good results in controlled trials.

Cluster C: Avoidant PD, Dependent PD, Obsessive-Compulsive PD

Individuals with these syndromes are usually described as anxious and socially insecure, but, compared to patients with other Personality Disorders, their ability to function in the workplace is usually better.
Table 3. The DSM-5 alternative model for Personality Disorders. Section III in DSM-5.

<table>
<thead>
<tr>
<th>Personality traits normal population</th>
<th>Pathological variants of traits</th>
<th>Facets of traits</th>
<th>6 Personality Disorders in alternative model: Antisocial, avoidant, borderline, narcissistic, obsessive-compulsive and schizotypal PDs (6 instead of 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Big Five”</td>
<td></td>
<td></td>
<td>Plus PD-TS (trait specified)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Neuroticism</th>
<th>Negative affectivity</th>
<th>Emotional lability</th>
<th>Borderline</th>
</tr>
</thead>
<tbody>
<tr>
<td>vs. Emotional Stability</td>
<td>Anxiousness</td>
<td>Avoidant, Borderline</td>
<td></td>
</tr>
<tr>
<td>Separation insecurity</td>
<td>Borderline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submissiveness</td>
<td>No specific PD associated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hostility</td>
<td>Antisocial, Borderline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perseveration</td>
<td>Obsessive-Compulsive</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Extraversion</th>
<th>Detachment</th>
<th>Withdrawal</th>
<th>Avoidant, Schizotypal</th>
</tr>
</thead>
<tbody>
<tr>
<td>vs. Extraversion</td>
<td>Intimacy avoidance</td>
<td>Avoidant, Obsessive-compulsive</td>
<td></td>
</tr>
<tr>
<td>Anhedonia</td>
<td>Avoidant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depressivity</td>
<td>Borderline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Restricted affectivity</td>
<td>Obsessive-Compulsive, Schizotypal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suspiciousness</td>
<td>Schizotypal</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Agreeableness</th>
<th>Antagonism</th>
<th>Manipulativeness</th>
<th>Antisocial</th>
</tr>
</thead>
<tbody>
<tr>
<td>vs. Agreeableness</td>
<td>Deceitfulness</td>
<td>Antisocial</td>
<td></td>
</tr>
<tr>
<td>Grandiosity</td>
<td>Narcissistic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attention seeking</td>
<td>Narcissistic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Callousness</td>
<td>Antisocial</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Conscientiousness</th>
<th>Disinhibition</th>
<th>Irresponsibility</th>
<th>Antisocial</th>
</tr>
</thead>
<tbody>
<tr>
<td>vs Conscientiousness</td>
<td>Impulsivity</td>
<td>Antisocial, Borderline</td>
<td></td>
</tr>
<tr>
<td>Distractibility</td>
<td>No specific PD associated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk taking</td>
<td>Antisocial, Borderline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Lack of) rigid perfectionism</td>
<td>Opposite pole: Obsessive-Compulsive</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Openness</th>
<th>Psychoticism</th>
<th>Unusual beliefs and experiences</th>
<th>Schizotypal</th>
</tr>
</thead>
<tbody>
<tr>
<td>vs Lucidity</td>
<td>Eccentricity</td>
<td>Schizotypal</td>
<td></td>
</tr>
<tr>
<td>Cognitive and perceptual dysregulation</td>
<td>Schizotypal</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DSM-5 and ICD point out the potential for change in Personality Status over time rather than it being a lifelong label. Mortality is elevated in PD and life expectancy is shortened. General health is worse, as are problems with relationships and with health care personnel [54].

There has been much criticism of the current categorical diagnostic model and efforts have been made to develop a dimensional system [54]. An alternative model for Personality Disorders (Table 3) has been presented in DSM 5 [55]. This model introduces the concept of Dimensional Personality Traits as one of the core criteria, apart from impairment in Personality Functioning, as well as a novel diagnosis, Personality Disorder – trait-specified (PD-TS). PD-TS is an alternate diagnosis to Personality Disorder not otherwise specified (PD-NOS) and addresses the clinical issues that patients with one Personality Disorder frequently satisfy the criteria for other Personality Disorders, as well as the lack of specificity of the PD-NOS diagnosis. The proposed model retains six distinct Personality Disorder Diagnoses from the current diagnostic model: Antisocial Personality Disorder, Avoidant Personality Disorder, Borderline Personality Disorder, Narcissistic Personality Disorder, Obsessive-Compulsive Personality Disorder and Schizotypal Personality Disorder. The remaining four PDs in the current diagnostic model are included in the PD-TS diagnosis (APA, 2013).

4.6 SICK LEAVE

Figure 1 shows that Sick Leave in Sweden has fluctuated considerably over time [11, 12]. There was a peak around the year 2000 and, from around 2004, Common Mental Disorders predominate diagnoses behind Sick Leave. Until then low back problems had been the predominant cause of sickness absence [10-12]. Common psychiatric disorders, such as Anxiety, Depression and Stress, are now the most common reason for Long-Term Sick Leave in European Countries [56, 57]. Sick Leave contributes to a large burden on the economies in Developed Countries. Only 20% of those who are on Sick Leave in Great Britain for longer than 6 months return to work [56, 57].
In Sweden there has been a large increase in Sick Leaves due to psychiatric diagnoses since 2009 (Figure 2), mainly Stress Disorders [12]. The risk factors in the workplace that has been discussed over time is mentally exhausting work, high demand, low control, and an imbalance between effort and reward [10].

Other researchers [58] hypothesize that individual characteristics and cultural contexts are important factors with impact on Sick Leave. They point out that there is time trends with different disorders dominating at different times and this is hard to explain by occupational causes. For instance, back problems caused a large Sick Leave peak in the 1970s in Britain.
and in the 1980s in Australia in the same way there was a peak in Sick Leave because of arm pain among office workers. [58, 59].

Individual factors are also important in the decision to take time off from work [59]. It has been suggested that when campaigns are started in order to reduce Stigma there is a risk that some individuals can medicalize transient minor symptoms. The little evidence available reveals an open field with a complex interaction between psychological, social, medical, and cultural factors [59].

In 2008, the Swedish government introduced the “Rehabilitation Guarantee” in order to support the counties in offering Cognitive Behavioral Therapy (CBT) for people with mild and moderate mental illness in primary care.

The evaluation of the Rehabilitation Guarantee, [60] concluded that CBT effects are beneficial for patients who are not on Sick Leave at the time when treatment is initiated; CBT reduces Absenteeism and the number of Drug Prescriptions during the year after the start of Treatment, while the number of health care visits increased somewhat. For CBT patients who are on Sick Leave when the treatment is started, there is no effect on Sick Leave, but on the other hand, a decrease in the prescribing of medicines and an increased number of health care visits. In general, there is little evidence that Treatments that are effective for Symptoms also have an effect on Sick Leave for patients already on Sick Leave.

4.7 QUALITY OF LIFE

Quality of Life (QoL) has been described as including subjective Well-Being, Life Satisfaction, Perceptions of Social Relationships, Physical Health, and the Level of Functioning in Daily Activities and Work [24]. It has also been suggested that one should distinguish between QoL and Health Status [61], and that the two seem to be different constructs from the viewpoints of the patients. Patients attach more importance to Mental Health than to Physical Functioning when ranking the Quality of Life, and vice versa regarding Health Status [61]. The Health-Related Quality of Life (HRQoL) measure is used as a complement to Symptom Assessment in Medical Research because it reflects broader aspects of the burden associated with Disease, such as Global Functioning in various areas of everyday living [5].

HRQoL consists of at least three domains, Mental Health, Physical Functioning and Social Functioning.
Primary care patients with Mental Disorders have a substantially impaired QoL [18, 62, 63]. The degree of impairment of the QoL varies with type of Mental Disorder, and is generally most pronounced for Mood Disorders [18, 64]. Different subtypes of Anxiety result in different degrees of impairment, with a more negative effect for Generalized Anxiety Disorder and Social Anxiety than for specific phobias [65]. Other variables besides psychiatric diagnoses and associated symptoms have different degrees of impact on the QoL. For example, older age is associated with more chronic disease and lower scores on the physical component of QoL [19] whereas social support and good economic conditions are associated with higher scores on all subscales on one widely used QoL instrument. QoL can be assessed using the SF-36 [66-68], a multi-dimensional instrument that measures eight aspects of health: Physical Functioning (PF), Role limitations due to Physical health problems (RP), Bodily Pain (BP), General Health (GH) perceptions, Vitality energy/fatigue (VT), Social Functioning (SF), Role limitations due to Emotional problems (RE) and Mental Health (MH). SF-36 scores can be standardized using a mean of 50 points with a standard deviation of 10 points. Items reflecting physical aspects of the QoL (i.e., the first four items) are often summarized in a Physical Component Summary (PCS). Correspondingly, the last four items covering mental aspects make up the Mental Component Summary (MCS).
5 AIMS OF THE PRESENT THESIS

The general aims of the present thesis were to investigate the effects of two group interventions for patients with Common Mental Disorders in primary care and to describe this group of patients with an emphasis on their Quality of Life. Specific aims were as follows:

5.1 PAPERS I AND II

The aim in the first two studies was to investigate, in a Randomized Controlled Trial (RCT), the effectiveness of two Transdiagnostic Group Treatments, CBT and MMI as add-ons to Care as Usual (CAU), compared to CAU for patients with Anxiety, Depressive and Stress-Related Disorders treated in a primary health care context. In Paper I, the primary outcome was QoL Mental Component Summary (MCS) Score of Short Form-36 (SF-36) [66-69], secondary outcomes were reduction of Anxiety Depressive and Obsessive-Compulsive Symptoms assessed with the Self-Rating Scale for Affective Syndromes (CPRS-S-A) [70], reduction of stress symptoms, the Perceived Stress Scale [71], while, in Paper II, the outcome was sick leave days.

5.2 PAPER III

The aim of Paper III was to describe primary care patients assessed to be in need of treatment for some Mental Disorder. The assessment focuses on their Diagnoses and Symptoms, Background Factors, Lifestyle, and Personality. A further aim was to elucidate how these variables are associated with the QoL.

5.3 PAPER IV

The aim of Paper IV was to describe the impact of different patient characteristics compared with the impact of psychological treatments on the QoL over time for patients with Mental Disorders in primary care.
6 ETHICS

We obtained Ethical Approval 2005-06-16 for the randomized clinical trial (Paper I and II) from the Regional Ethics Committee in Stockholm, Dnr 2005/447-31. The approval was amended in 2006-06-21 regarding an additional follow-up assessment 6 months post treatment (Paper I) and in 2009-05-19 regarding an enquiry for permission to use sick leave data (Paper II).

A new approval was obtained in 2015-02-12, from the Regional Ethics Committee in Stockholm, Dnr 2015/58-32, regarding comparisons of patient personality characteristics, background factors, and QoL (Papers III and IV).
7 STATISTICS

7.1 PAPER I
The data were analyzed using intention-to-treat. The primary end points were analyzed using a linear mixed model in which the responses at post assessment and the 1-year follow-up were included as dependent variables, and group, time and baseline values of the response variable were added as fixed factors in the model. The intercept of each subject was added as a random factor. Based on the linear mixed model, inferences could be made concerning the difference between groups and over time. Effect sizes were calculated using Cohen’s $d$. In addition to the primary analyses, several sensitivity analyses were performed to assess the robustness of the results.

7.2 PAPER II
A mixed model to analyze the effect of treatment and time was not considered useful since the residuals were not normally distributed, the number of days of sick leave per month usually being 0 or 30 days. Our primary outcome measure was therefore defined as odds (odds ratios, ORs) for being sick-listed or not in a comparison between groups at different points in time, adjusted for whether one was sick-listed before the start of the trial.

7.3 PAPER III
To evaluate the influence of the different variables, such as Life-style, Education, Personality or Diagnoses on the MCS and PCS Scales of the SF-36, a linear ANOVA/regression was performed. All continuous variables were dichotomized using a median-split. The model selection was based on the Aikaike Information Criterion. The OC Scale in CPRS-S-A is not included in the regression analyses in Papers III and IV since the questions are shared with the Anxiety and Depression Scales, except for two questions with a focus on OC.

7.4 PAPER IV
The variables measured before treatments were used to predict: (1) the two Summary Component Scales of the SF-36 at baseline. The same variables were also used together
with the variable “treatment”, CBT, MMI, or CAU, to predict: (2) the outcome of the two Summary Scales of the SF-36 one year after treatment and the outcome of the two Summary Scales of the SF-36 one year after treatment. Linear backwards stepwise ANOVA/regressions were performed in which the model selection was based on the Aikaike information criterion. All continuous predictor variables were dichotomized using a median-split.
8 MATERIAL AND METHODS

Trial Design
The trial was an RCT with two group interventions (CBT and MMI) with CAU as control. The randomization was computer generated by a statistician who was not otherwise involved in the study.

Participants and Recruitment
The patients were recruited for a randomized controlled trial [72], comparing two different group interventions with care as usual for patients with mental illness. GPs were instructed to ask all patients aged 18 - 65 years who they suspected to have Common Mental Disorders including, Depression, Anxiety, Stress and Somatoform Disorder to participate, and 278 were referred to the study. Patients were assessed using the structured clinical interview for DSM-IV Axis I and Axis II (SCID I and SCID II), with the latter refers to Personality Disorders [73]. Exclusion criteria were Bipolar or Psychotic Disorder or severe Personality Disorder. They were judged to be at risk of committing suicidal acts if they had undergone MMI earlier. In Paper II, patients were excluded from the analysis if they were recipients of a permanent or temporary Disability Pension at any time during the study period, before or after the randomization, or if they were not employed.

Interventions
The group interventions were provided in groups of six participants. During the period of group therapy, the GPs cared for the participants in the same way that they cared for patients in the control group. None of the interventions had a specific focus on work ability.

Cognitive-Behavioural-Based Therapy
Group CBT was based on generally acknowledged cognitive and behavioural treatment principles from the domain of Anxiety and Mood Disorders. In this protocol, the group CBT treatment comprised one 120-minute group session per week for 12 weeks led by one of two licensed clinical psychologists with training and experience in delivering CBT. The first four sessions were focused on, respectively, developing conceptualizations of patients’ problems and psycho-education and exposure interventions for Anxiety Disorders and behavioral activation for Depression. Sessions 5 to 11 were focused on exposure to feared
stimuli and emotional awareness training. The final session was focused on acquiring new skills to handle risk situations for relapse.

**Multimodal Intervention**

This was a group intervention following a protocol created by one of the authors (Ruslan Savitskij) consisting of a mix of existing group interventions and exercises utilized in a variety of therapeutic schools. Prior to the start of group treatment, participants met an assistant nurse for an individual appointment where a brief description of the treatment was given. During this session, the nurse also collected detailed information about the participants’ psychiatric problems and participants were asked to write down their goals and ideas for solutions to their problems. The group intervention comprised 150-minute group sessions twice a week for 6 weeks and sessions were led by one of three assistant nurses with only brief training. The main components of the treatment in the first week were a unified goal setting among the group members, psycho-education concerning thoughts, emotions, and behaviors that are common in persons with Depressive and Anxiety Symptoms. During the second week of treatment, the participants were introduced to an exercise where one participant shares a personal problem with the group and obtains feedback. A focus was also on the importance of physical training and the participants were taught to do a few yoga exercises. The focus of the third and fourth weeks of the intervention was on understanding the difference between emotions and thoughts and strategies concerning how to deal with conflicts were presented. During the fifth week, participants were asked to invite important people in their lives to attend two sessions to work on team building. The participants and their guests were encouraged to take part in small group activities. During the final two sessions in the sixth week, strategies for handling difficult thoughts and emotions in highly stressful situations were presented. Following group therapy, each participant also had two additional individual sessions with the assistant nurse to discuss individual goals set prior to group therapy. Three assistant nurses administered the MMI intervention. They had no formal psychotherapeutic education and their training prior to this study was participation in an MMI group treatment as a member, and subsequently, as an observer, except for one of the assistant nurses who had administered the intervention for a couple of years at the Primary Health Care Center prior to the study. They were thoroughly recruited and selected on the basis of their personal interest and judged suitability for the task. All three assistant nurses received weekly supervision by the originator of MMI or a group therapist.
Care as Usual

Participants in the control group were given Care As Usual, CAU, by GPs at the Primary Health Care Centre consisting of appointments with GPs who prescribed medication and sick-listing when necessary, with referrals to the counselor at the Primary Health Care Center and, more rarely, to a Psychiatric Clinic.

Outcomes

Since the participants had different psychiatric symptoms and diagnoses, the Mental Component Summary (MCS) Score of Short Form 36 (SF-36) [66-69] was used as the primary outcome in Paper I and, in Papers III and IV, the Physical Component Summary (PCS) with subcomponents was used in addition to the MCS and, in Paper II, the primary outcome was sick-listing. Secondary outcomes (Paper I) were measures of Anxiety Depressive Symptoms, Obsessive-Compulsive Symptoms and Stress Symptoms. Assessment points were at baseline, post-treatment, and at the 1-year follow-up. Sick-listing data were obtained from the Social Insurance Agency (SIA). For each month, from 24 months before randomization to 24 months afterwards, the number of sick leave days was calculated as the sum during the preceding 30 days.

Sample Size

Assuming a treatment effect of 7% points on the MCS and a SD of 15% points, a minimum of 74 persons per group would be needed to achieve an 80% statistical power at the 5% significance level (double sided). With an expected dropout rate of 10%, ~80 patients were randomly allocated to each treatment arm.

Blinding

No blinding was used.

Trial procedures

A baseline assessment (DSM-IV Axis I and II Disorders), along with the Alcohol Use Disorders Identification Test (AUDIT) [74] to detect risky alcohol habits was performed by two of the investigators [72]. Self-Rating Scales, PSS and CPRS-S-A were used and information on such background factors as education, family situation, social support, and employment were collected. To measure Personality, the Health-Related Personality Inventory (HP5i) [75, 76] was used. Physical activity was assessed (kcal/kg/24h) by letting the patients indicate on a nine-step scale their daily activity levels [77, 78]. Written
informed consents were collected from all participants. A total of 82% ($n = 200$) provided data at the post treatment assessment and 96% ($n = 235$) completed the assessment at the 1-year follow-up. For 24 participants, the 1-year follow-up assessment was delayed 4–19 months.
9 RESULTS

**Assessed for eligibility (n=278)**

- Excluded before randomization (n=33)
  - Not meeting inclusion criteria (n=9)
  - Declined to participate (n=7)
  - No contact when invited (n=17)

**Randomized (n=245)**

- **Allocated to MMI (n=80)**
  - Received allocated intervention (n=67)
  - Did not receive allocated intervention (13)
    - n=7, did not start, no contact
    - n=6, dropped out, reason:
      - Demanding treatment (1)
      - Unknown (2)
      - Moved (2)
      - Schedule problem (1)

- **Allocated to Care As Usual (n=81)**

- **Allocated to CBT (n=84)**
  - Received allocated intervention (n=74)
  - Did not receive allocated intervention (10)
    - n=4, did not start, no contact
    - n=6, dropped out, reason:
      - Demanding treatment (1)
      - Unknown (4)
      - Scheduling problems (1)

**Post-assessment, 2 weeks:**
- Lost to follow-up (n=1)
- Assessed (n=66)

**One year follow-up:**
- n=62 Completers
- n=2 Noncompleters
- Late “1 year” follow-up:
  - 4-19 months late
  - n=4 Completers
  - n=8 Noncompleters

- n=66/67 completers available data

**Analyzed n=76 of 80**
- 4 did not come to assessment

**Assessed for sick-listing in Paper II**

- Excluded (disability pension, unemployed or self-employed) (n=35)
- Assessed (n=45)

- Excluded (disability pension, unemployed or self-employed) (n=20)
- Assessed (n=61)

- Excluded (disability pension, unemployed or self-employed) (n=26)
- Assessed (n=58)

Figure 3. Participant recruitment flow chart.
9.1 PAPER I-II

A participant recruitment flow chart is shown in Figure 3. Background data showed that most participants were middle-aged women with an average to high educational level. Mood Disorders were the predominant diagnoses among the participants (n = 139; 57%) and in this group major Depression was the most common diagnosis (73.4%). Anxiety Disorders were diagnosed in 91 participants (37.3%) with Unspecified Anxiety being most prevalent (37.4%), followed by Specific Phobia (30.8%). For about one-fourth of the participants, no diagnosis according to DSM-IV criteria was present at the time of the interview. The primary outcome measure was the MCS of SF-36. The mean improvement at post-treatment and the 1-year follow-up was significantly higher among participants in the MMI group than among those in the CBT and CAU group, table 5. CBT participants were significantly more improved than CAU participants. On all three subscales of the CPRS-S-A and PSS, MMI showed a significantly higher treatment effect than did both CBT and CAU, whereas CBT did not differ from CAU on any of these measures. The effect size (Cohen’s $d$) between MMI and CAU groups was moderate on SF-36 MCS, Depression and Stress (PSS). The effect sizes between MMI and CAU were small on Anxiety, OCD (Table 6).

Table 4. Background characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>MMI (N = 80)</th>
<th>CBT (N = 84)</th>
<th>CAU (N = 81)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (SD)</td>
<td>44.3 (9.5)</td>
<td>43.3 (10.3)</td>
<td>45.0 (9.5)</td>
</tr>
<tr>
<td>Women, n (%)</td>
<td>68 (85)</td>
<td>63 (75)</td>
<td>67 (82.7)</td>
</tr>
<tr>
<td>Mean BMI (SD)</td>
<td>26.7 (5.9)</td>
<td>25.7 (3.8)</td>
<td>25.9 (4.6)</td>
</tr>
<tr>
<td>Smokers, n (%)</td>
<td>18 (22.5)</td>
<td>30 (35.7)</td>
<td>28 (34.6)</td>
</tr>
<tr>
<td>Education (highest)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary school</td>
<td>17 (21.3)</td>
<td>17 (20.2)</td>
<td>20 (24.7)</td>
</tr>
<tr>
<td>Secondary school</td>
<td>29 (36.2)</td>
<td>41 (48.8)</td>
<td>37 (45.7)</td>
</tr>
<tr>
<td>University/college</td>
<td>34 (42.5)</td>
<td>26 (31.0)</td>
<td>24 (29.6)</td>
</tr>
<tr>
<td>Psychiatric diagnoses (DSM-IV)*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mood disorders</td>
<td>52 (65.0)</td>
<td>46 (54.8)</td>
<td>41 (51.2)</td>
</tr>
<tr>
<td>Anxiety disorders</td>
<td>33 (41.2)</td>
<td>32 (38.1)</td>
<td>26 (32.5)</td>
</tr>
<tr>
<td>Somatoform disorders</td>
<td>5 (6.2)</td>
<td>2 (2.4)</td>
<td>3 (3.8)</td>
</tr>
<tr>
<td>Eating disorders</td>
<td>2 (2.5)</td>
<td>1 (1.2)</td>
<td>3 (3.8)</td>
</tr>
<tr>
<td>Alcohol dependence</td>
<td>1 (1.2)</td>
<td>0</td>
<td>1 (1.2)</td>
</tr>
<tr>
<td>Not fulfilling psychiatric disorder criteria</td>
<td>11 (13.8)</td>
<td>20 (23.8)</td>
<td>24 (29.6)</td>
</tr>
</tbody>
</table>
For all three groups, the majority of patients had 0 sick leave days the month before randomization, whereas 20 days was the second most common sick leave pattern. For all three groups, sick leave days increased up to the date of randomization, and decreased, in a uniform manner, up to two years after the beginning of the trial. There was no clear pattern regarding the relationship between groups at different points in time. We did not find lower odds for sick listing with active treatment compared with usual care (Table 7) and CBT compared with usual care had a significantly elevated OR for sick listing at 24 months.
Table 7. Odds ratios (95% CI) for being sick listed as comparison between groups at different times, relative to randomization.  

<table>
<thead>
<tr>
<th>Comparison</th>
<th>6 months</th>
<th>p-value</th>
<th>12 months</th>
<th>p-value</th>
<th>24 months</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MMI vs. usual care</td>
<td>1.17 (0.41:3.33)</td>
<td>0.77</td>
<td>1.04 (0.38:2.76)</td>
<td>0.94</td>
<td>1.71 (0.49:6.39)</td>
<td>0.40</td>
</tr>
<tr>
<td>CBT vs. usual care</td>
<td>1.91 (0.70:5.44)</td>
<td>0.22</td>
<td>0.84 (0.32:2.22)</td>
<td>0.73</td>
<td>3.39 (1.19:12.43)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

Note: \(^1\)Adjustments were made for the number of days on sick leave in the month before randomization.

Figure 4. Mean number of sick leave days at different points in time, relative to randomization for the three groups. CAU refers to “care as usual”.

9.2 PAPERS III-VI

Compared to the Swedish reference group, problems with managing current expenditure during the last year were more common in the study group. Fewer had someone to share their innermost feelings with, compared to the Swedish reference group. More patients were overweight and smoking was more common. In Table 4 diagnoses are described. In the study group, 21.2% had one PD and 8.7% had two or more. The most frequent ones were OC PD (13.7%) and avoidant PD (12%). The third most common Disorder was Depressive (8.3%), while the others were below 5%; Passive-Aggressive 4.2%, Borderline 2.9%, Narcissistic 1.3%, Dependent 0.8% and Antisocial 0.4%.

Compared to the population data on the Personality Scales, with 50 as the mean for all scales, the study group was characterized by Lower Hedonic Capacity (Extraversion) (M = 44.1, SD 11.2, p <0.001) and Higher Degrees of Negative Affectivity (Neuroticism) (M = 54.3, SD = 9.8, p <0.001). The group was characterized by a lower degree of Antagonism (opposite of Agreeableness) (M = 46 SD= 9.6, p <0.001). The mean score for Impulsivity
(opposite of Conscientiousness) was 51.4, SD 11.3, p = 0.044), and, for Alexithymia (opposite of Openness) it was 48.7 (SD = 9.2, p = 0.034).

Figure 4 is a spider diagram showing average scores on the SF-36 dimensions compared to the Swedish Normative Data. While the group scored almost the same as the population on the Physical Functioning Scale, the points on all other scales were markedly reduced – almost halved. The group scored almost the same as the population on PCS, M = 46.43, while MCS was almost halved, 25.05, compared to the general population.

In the regression model for MCS before treatment, Mood Disorder and the degree of Depressive Symptoms, together with Stress, were most important and had a negative impact. Having an Anxiety Disorder and a high degree of Anxiety Symptoms also had a negative impact. Among background factors, lack of an Economic Buffer had a negative influence. No PD was included. Among Personality Traits, Impulsivity, as a facet of low Conscientiousness, had a negative impact in the Regression Model. In the Regression Model for PCS as the outcome variable, being on Sick Leave was the strongest factor, and with a negative effect, followed by Being Employed/At Work, with a positive effect. High Stress Levels had a positive effect, while a high degree of Anxiety Symptoms and high BMI were negatively associated with PCS. Physical Activity had a small positive effect.

At 12 months (Paper IV), a clear change in the pattern of predictors had appeared (Table 8). For MCS, two important predictors were now included in the model, Being Employed (positive) and Being Born Outside of Sweden (negative). Among the Diagnoses and Symptoms, having an Anxiety Disorder still had a negative impact, in contrast to Mood Disorder and Depressive Symptoms. One PD (OC) with a negative impact was included in the regression model.

For the Summary Score PCS, Being on Sick Leave at the time for the start of the study, having a high degree of Anxiety Symptoms and a high BMI remained as negative predictors. Being a Daily Smoker predicted a lower PCS one year after treatment. In contrast to before treatment, two Personality Traits were now included in the model, Hedonic Capacity and Impulsivity, both with positive values. The positive effect of Stress remained.

The effect of Active Treatment, compared to the Control Condition, on QoL after 12 months, was strong for MMI with a high and positive influence on MCS and on a level with the highest in the Regression Models. CBT had a positive impact on MCS, but a small negative impact on PCS.
Figure 5. SF-36 dimensions for the study sample compared to Swedish norms. BP (Bodily Pain), RP (Role Physical), MH (Mental Health), RE (Role Emotional), SF (Social Functioning), VT (Vitality -Energy/Fatigue-), GH (General Health Perceptions), PF (Physical Functioning).
Table 8. Results of the regression analyses for MCS and PCS before treatment and 12 months after treatment. Regression coefficients and p-values are shown for the patient characteristics and for belonging to one of the treatment groups CBT or MMI. P-value in parenthesis.

<table>
<thead>
<tr>
<th>Variables in the final regression model</th>
<th>MCS Before treatment</th>
<th>MCS 12 months after treatment</th>
<th>PCS Before treatment</th>
<th>PCS 12 months after treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Background</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sick leave</td>
<td></td>
<td></td>
<td>-6.51 (&lt;0.001)</td>
<td>-3.44 (0.007)</td>
</tr>
<tr>
<td>Employed</td>
<td>4.26 (0.015)</td>
<td>4.21 (0.012)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Born outside Sweden</td>
<td>-6.72 (0.008)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical activity</td>
<td></td>
<td>2.46 (0.083)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
<td>-2.48 (0.067)</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td></td>
<td>-2.81 (0.050)</td>
<td>-1.71 (0.140)</td>
</tr>
<tr>
<td>Lack of economic buffer</td>
<td>-2.44 (0.091)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DSM-IV AXIS I and symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Affective Disorder</td>
<td>-8.87 (&lt;0.001)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety Disorder</td>
<td>-3.20 (0.018)</td>
<td>-2.86 (0.099)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Somatoform Disorder (10 patient of 245)</td>
<td></td>
<td></td>
<td>5.63 (0.083)</td>
<td></td>
</tr>
<tr>
<td>Depressive symptoms</td>
<td>-7.54 (&lt;0.001)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety symptoms</td>
<td>-2.68 (0.063)</td>
<td>-3.07 (0.043)</td>
<td>-2.77 (0.027)</td>
<td></td>
</tr>
<tr>
<td>Stress</td>
<td>-5.14 (0.001)</td>
<td>3.13 (0.035)</td>
<td>2.40 (0.046)</td>
<td></td>
</tr>
<tr>
<td>DSM-IV AXIS II</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OC PD</td>
<td>-3.69 (0.118)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personality</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hedonic capacity</td>
<td></td>
<td></td>
<td>3.83 (0.002)</td>
<td></td>
</tr>
<tr>
<td>Impulsivity</td>
<td>-2.50 (0.053)</td>
<td></td>
<td>1.78 (0.131)</td>
<td></td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMI</td>
<td>7.13 (&lt;0.001)</td>
<td></td>
<td>1.83 (0.196)</td>
<td></td>
</tr>
<tr>
<td>CBT</td>
<td>-4.13 (0.041)</td>
<td></td>
<td>-1.60 (0.237)</td>
<td></td>
</tr>
</tbody>
</table>
10 DISCUSSION

With a background of increased awareness of mental problems among patients in primary care, including serious problems with Sick Leave, primary care has an urgent needs to treat mental illness in an effective manner. Therefore, we made an attempt in 2002 to improve the care for patients with Common Mental Disorders. We offered Group Intervention, in addition to visits to GPs. Assistant nurses, without therapy training, led manualized group interventions for patients with Common Mental Disorders. After a few years it was necessary to evaluate this local manual. CBT was, at this time, the therapy for which there were evidence-based manuals available. However, there is a substantial comorbidity between Anxiety Disorders and Mood Disorders. David Barlow [25] and his research group had at this time developed a Transdiagnostic CBT Protocol (Individual Treatment) for patients suffering from both disorders. We aimed to investigate both the Local Manual (MMI) and a Group Manual based on David Barlows Unified Protocol for Common Mental Disorders and evaluate the effects of these treatments on QoL, symptoms and effects on Sick Leave. We also wanted to increase our knowledge concerning patient characteristics such as Personality, PD and their impact on the QoL both at inclusion, but also one year after treatment.

10.1 METHODOLOGICAL CONSIDERATIONS

10.1.1 Paper I

We chose to perform a Randomized Controlled Study because it is considered to be the best method to minimize the risk of bias and compare Care as Usual with Research Interventions in a scientifically robust way at a Primary Care Center. Two considerations were discussed early on in the research group. Blinding of the Interventions to the participant is desirable, which, however, is in this study was not possible since the Interventions delivered were distinctly different and this was apparent not only to the therapist, but also to the patients.

There were only two therapists for the CBT-based intervention and three assistant nurses leading the MMI. This number of therapists is very low and constituted a risk for the project. It also raises questions regarding the generalizability of the results.

Effectiveness Trials measure the effect under “real world” clinical settings. We wanted to be as close as possible to the natural conditions of a primary care setting. Therefore, we asked the GPs to refer all eligible patients from their ordinary clinical work i.e. patients with Anxiety, Stress, and/or Depressive Symptoms.
We used QoL as a primary outcome since we mixed patients with different diagnoses although this also increased the challenge since QoL as the outcome suffers from a lack of sensitivity and is subject to patients’ Coping Abilities, which also tend to obscure measurements of the result.

The locally Developed Manual for Group Intervention, MMI, had been created by one of the authors, Ruslan Savitskij, psychiatrist, and the intervention had been used for several years with promising results in a Psychiatric Clinic.

The CBT-based unified protocol was created for individual treatments. Before the trial could start we had to adjust the Protocol to a Group Format. This work was done by two young psychologists under the supervision of senior researchers. There was not enough time for them to practice their skills with the manual for more than one Group Treatment each for the two psychologists. This could be a reason to explain the results of the CBT Based Group Therapy.

10.1.2 Paper II
The strengths of the study are the Randomized Design and the availability of registry data on Sick Leave for all participants. An important limitation is that the study was not designed primarily for addressing the sick-listing issue, and therefore we can not evaluate its statistical power in this respect; being sick-listed was not an inclusion criterion, which probably reduced the study’s ability to demonstrate effects of Psychosocial Interventions on Sick Leave. It could have also been useful to include measures other than days on Sick Leave, e.g. Self-Reported Work Ability, as in the Work Ability Index [79]. Other limitations are the small number of therapists (two and three respectively), which restricts the generalizability to other settings, and differences between CBT and MMI in terms of, for example, Total Therapy Time.

10.1.3 Papers III and IV
One of the limitations of our study is that the group was assessed at a time in their lives when they tended to be in an acute phase of worsened psychological well-being. It would be interesting to study such primary care patients, who often have recurrent or chronic problems, at other points in time to see if the pattern of associated factors would change. Another limitation is that the referral to the study was dependent to a high degree on the individual physician’s judgement. Finally, there is an overlap between the Assessment of Depressive Symptoms in CPRS-S-A and items in the MH Subscale of SF-36, targeting Depressive Symptoms. On the other hand, there were, in general, low scores also in
domains not directly reflecting symptoms, such as Social Functioning and Role Emotional. Furthermore, we did an Additional Analysis with these two subscales as dependent variables and found the same two most important predictors for both, i.e., Mood Disorder and Stress, as when MCS was used. An instrument focusing on Life Satisfaction rather than Psychological Symptoms, such as the Quality of Life Inventory (QOLI) [80], would have been an interesting complement. A strength of the study is its clinical validity since it was performed in an ordinary primary care practice. Another strength is that the group was extensively examined for Background Factors, Lifestyle, Symptoms, Personality, and Psychiatric Diagnoses.

In Paper IV, we compared predictors for QoL both at inclusion and one year after treatment, and we could also compare the effect of treatment with other predictors. One of the limitations of the study is that we only used a Self-Report Measure for QoL and for many of the predictors such as Lifestyle, Symptoms and Personality. In an unblinded study, there can certainly be a bias regarding post treatment QoL-data due to patient reporting being influenced by a knowledge of Allocation to Active Treatment or not, sometimes referred to as the Hawthorne Effect [81]. Multiple Analyses of correlations made between a number of variables and three treatment arms were performed. Thus, it is possible that some of the statistically significant correlations might still be due to random events. We conducted Complementary Analyses without Symptom Scales and without treatment and found that the same predictors applied to the Regression Models.

10.2 GENERAL DISCUSSION AND MAIN FINDINGS

10.2.1 Group treatments

Are group treatments led by assistant nurses in primary care effective treatments for CMDs in primary care?

One important aspect of the studies in this thesis was to elucidate whether or not staff without extensive psychiatric training could deliver interventions that led to substantial improvements. Based on data in our trial, I conclude that it appears to be effective to use the MMI group intervention (Paper I) in addition to CAU in primary care for patients with CMDs regarding their psychological well-being.

Irrespective of the outcome (Mental Components of QoL, Symptoms of Stress, Depression or Anxiety), there is a dramatic improvement over time in all three Treatment Groups, including CAU. This might be partly due to the fact that patients in the CAU group also received some Limited Treatment and Attention, but it probably merely reflects the natural course of mild/moderate Depression and Anxiety with Regular Fluctuations. Since patients
are more prone to seek health care when the symptoms are worse, there is certainly a regression towards the Mean-Like Effect [82] that can be considerable, as indicated by the large “response” in the CAU group. This is also demonstrated in Figure 4 where the frequency of Sick Leave is shown, before, at and, after inclusion in the trial for the three treatment groups. This illustrates the utmost importance of including a Control Group (waiting list, CAU or Placebo) in trials of conditions with this type of natural course. Without a control group, a comparison of the state of health before and after therapy can be grossly misleading. Also, conclusions regarding non-inferiority between active treatment arms can be difficult to draw unless there is a control group showing that there is indeed an effect, as well as the magnitude of the active interventions.

Mixing diagnoses in the same trial introduces a risk of dilution of a clinically relevant effect for a specific diagnosis. However, when a positive effect is indeed demonstrated, the results represent an advantage for small primary care centers. This is particularly important since the patient mix encountered in primary care is that of patients with less severe, but often multiple, CMDs. Today CBT offers many different evidence-based manuals for various Anxiety Disorders as well as specific manuals for Depression. At a smaller primary care center it is harder for a single therapist to keep many diagnosis-specific manuals up to date and furthermore, for group treatment, the waiting time for filling a group with patients with a single diagnosis can be extensive. Many patients in our sample (50%) had both Anxiety and Depressive Disorders, which has been demonstrated in many previous studies (ref), and increases the need for Transdiagnostic Treatments.

The difference in the mean score for the primary QoL outcome (MCS SF-36) between MMI and CAU was 7.1 post-treatment. The difference between the treatment groups in symptom reduction on the CPRS-S-A Depression Scale, which is similar to the Montgomery-Åsberg Depression Rating Scale (MADRS), was 4.3 post-treatment. This can represent a clinically relevant effect which is well in line with typical results from the treatment of Depression with SSRI where post-treatment differences compared to placebo on the MADRS Scale is typically between 1 and 3 [83]. Effect sizes (Cohen’s d) for SSRI-treatment of moderate Depression are typically around 0.3-0.4 [83]. The effect size (Cohen’s d) between groups (MMI versus CAU) was 0.55 for the secondary outcome measure MADRS. This is to compare with CBT treatment for Depression in relation to CAU which has an effect size of g=0.60 according to a recently published meta-analysis [84].

There is a lack of therapists with sufficient training to treat these patients in primary care. Using staff with shorter training as a complement to highly trained therapists would optimize resources, thereby enabling the latter to focus on the more severe cases, while those with less training could take on the milder cases. However, MMI group therapy has been shown to be effective in a single centre when supervised by the inventor of the module. There is a need to show, in a controlled setting, that these results can be confirmed when the same module is used elsewhere without the same supervision. A similar model is
implemented in British Psychiatric Outpatient Clinics under the Improving Access to Psychological Therapies [85] Program comprising therapists with only little training giving treatments as a first step. In our study, MMI as a group intervention led by non-expert therapists showed promising results as a treatment for mild to moderate Mental Disorders in primary health care. The CBT group treatment based on the Unified Protocol was less effective. One possible explanation is that our manual was based on a unified treatment manual for individuals and adapted to group therapy with very little training and assessment before the trial started.

10.2.2 Sick Leave

**Do effective treatments reduce Sick Leave?**

In our study, odds for sick listing after active treatment were not significantly lower compared to the usual care condition (Table 7). Also, CBT had a significantly elevated odds ratio (OR) for sick-listing at the 24-month follow-up compared with care as usual (the result should be interpreted with caution due to it being based on one measurement point, a low significance level, and multiple comparisons).

One central finding of this thesis was that although patients reported an improvement in terms of psychiatric symptoms and QoL, they did not reduce their risk of being on Sick Leave (Figure 5). These results are in line with current research [10, 60]. Reductions of Sick Leave do not automatically follow reductions in symptoms. So far, Return-To-Work Manuals have not improved Return-To-Work Rates [10, 57], although a few trials have found positive effects. There may of course be different effects on different outcomes, but there is also a possibility that such subjectively reported outcomes as Disease Symptoms or QoL measures are overestimated in a study where patient allocation to the tested therapies cannot be concealed. In contrast, Sick Leave as an outcome measure is more robust and less likely to be biased by patient expectations and Hawthorne-Like Effects [81].

An important aim for future research is also to gain more knowledge about the mechanisms of Sick Leave and to investigate whether interventions designed to promote return to work for patients with CMDs could lead to a faster reduction of Sick Leave. In conformity with Paper II of this thesis, the previous literature on this topic is not very encouraging. Several studies have shown none or small effects of return-to-work interventions [86, 87] and it has been debated whether other factors rather than the CMD might play a larger role in the risk of sick listing for Mental Disorders [57, 58, 88]. Such factors could include Sick Leave recommendations from the National Board of Health and Welfare, but also how the primary health care system is organized, i.e., where GPs are under pressure to prescribe Sick Leave to promote short-term patient satisfaction while the costs of Sick Leave are
carried by the Swedish Insurance Agency. Also, as stated by Henderson [88], social, medical, psychological, and cultural factors might affect Sick Leave. Considering the massive societal burden of Sick Leave costs, more research on factors that influence Sick Leave in primary care patients with CMDs is urgently needed.

10.2.3 Factors associated with and predicting QoL

Patient characteristics were measured at inclusion (diagnosis, lifestyle, background factors). The association of these data to MCS and PCS was described in paper III. In Paper IV the same data together with the variable treatment as a comparison, were used to predict MCS and PCS one year after treatment. The most important finding were that psychological symptoms, mainly depressive symptoms, were most important for determining well-being at inclusion. On the other hand, being employed and being Swedish-born were the most important long-term predictor. In addition, Anxiety Disorder and Anxiety Symptoms were represented most frequently in the four final models, before and after treatment for both MCS and PCS. Based on previous research one might expect Neuroticism to be an important variable. Neuroticism, a Personality Trait associated to Anxiety and QoL, was not included in the final model, and this could possibly be because of the association with Anxiety Disorders or Symptoms which by nature could be stronger competitors. The strong positive impact of the MMI on MCS was already shown in Paper I, and it was the strongest positive predictor.

Time to pay attention to Personality Disorders and Traits in Primary Care?

Compared to the general population, the patient sample in our study scored about half on all of the SF-36 Scales. Personality Disorders (PDs) were common (29.9 %), with obsessive-compulsive PD being the most frequent (13.7%) and avoidant PD being the second most frequent PD (12%). Sample scores for the Personality Traits Extraversion (Hedonic capacity), Conscientiousness, and Agreeableness were lower whereas scores for Neuroticism and Openness were higher, compared to the general population. OC PD was a negative predictor for the MCS, together with Anxiety Disorder one year after treatment. New research shows the importance of Personality Traits, associated illness and the cost for society [89, 90]. The trait Neuroticism has been well-studied and found to be very costly due to its associations with both Somatic and Mental Disorders [32, 90]. The Netherlands Mental Health Survey and Incidence Study (NEMESIS) compared a group with high levels of Neuroticism with a normal reference group. The study found that a high degree of Neuroticism was associated with a higher frequency of Mental Disorders and
Somatic Diseases such as Asthma, Cardiovascular Disease and Irritable Bowel Syndrome (IBS), and therefore greater costs. Also, Neurotic Patients were found to express medically unfounded somatic complaints more often. Since Neurotic Patients use more health services, costs for visits to General Practitioners and Physiotherapy, as well as additional costs for Social Services, were included [32, 90].

Considering the associations with CMDS and somatic diseases and that Neuroticism often precedes the development of these Disorders one potential area for future research is to investigate whether or not early interventions for primary care patients with high levels of Neuroticism could prevent the development of CMDs and decrease the use of somatic health care and the costs.
11 CONCLUSIONS

- Transdiagnostic group treatment led by assistant nurses in a primary care setting can be effective for patients with CMD.
- A decrease in psychological symptoms and increased well-being did not seem to have an effect on Sick Leave.
- For primary care patients with mild to moderate Mental Illness, Mood Disorder and Depressive Symptoms were the strongest factors associated with negative influence on the MCS.
- Effective treatment and being employed had the strongest positive impact on MCS one year after treatment. PD had the strongest negative impact together with Being Born Outside Sweden one year after treatment.
- Increased priority for the treatment of CMD in primary care is of great importance.
There are several clinical implications of the studies described in this thesis. First and foremost, this thesis adds to the previous body of literature demonstrating that one of the largest patient groups in primary care, i.e., those with CMDs, can achieve large improvements in the QoL if offered a brief and structured psychological treatment. It is there for essential, and in line with recommendations from example NICE and the NBHW, that primary care is organized in a way that makes implementation of psychological treatment possible. This requires staff with adequate competence in detecting CMDs and conducting psychiatric assessments, as well as accessibility to trained therapists. One major challenge for primary care to achieve this aim is to ensure that continuous medical education is provided and that mental health care professionals, e.g., psychologists, are hired to a larger extent than today. One important aspect of the studies in this thesis was that staff without extensive psychiatric training could deliver therapies that led to large improvements. This might mean that an increased accessibility to effective psychological treatment could be achieved, in spite of a shortage of highly skilled CBT psychologists, if nurses are given a brief training and regular supervision. It is, however, important that psychologists with an overarching responsibility for the assessment procedures and treatment processes are also well represented in the primary care work force.

If psychological treatment would be implemented on a large scale in primary care there would probably be substantial positive effects in terms of general health in the population, but it would also put less strain on GPs and perhaps also reduce the overutilization of somatic health care resources observed in patients with CMDs [32, 90]. Implementation of evidence-based psychological treatment would thus likely be of high value for the patient, the health care system, and society as a whole.

One central finding of this thesis was that although patients reported an improvement in terms of psychiatric symptoms, they did not decrease their sick leave time. That is, despite reporting that they were feeling better, they remained on Sick Leave.

Thus, we found interesting results from the local variant of the group therapy while the group therapy based on CBT was less conclusive. Partly as a consequence of these results, we have started new trials at Gustavsberg.
**13 SUMMARY IN SWEDISH**


**Syfte:** Målet med avhandlingen var att undersöka följande: a) Effekterna av två olika gruppbehandlingar inom primärvården för vanliga psykiska åkommor (Studie I), b) effekterna av effektiva behandlingar inom primärvården på sjukfrånvaro (Studie II), c) sambanden mellan patientegenskaper och livskvalitet (Studie III) och d) Hur patientvariabler respektive psykologisk behandling kan förutsöga livskvalitet vid ettårsuppföljning (Studie IV).

**Metod:** En stor randomiserad kontrollerad studie genomfördes. I Studie I jämfördes effekterna av en transdiagnostisk gruppbehandling baserad på kognitiv beteendeterapi (KBT) (n= 80) och en grupp som fick behandling med Multimodal Intervention(MMI) ledd av undersköterskor (n= 84) med effekterna av sedvanlig behandling (n=81). Studie II jämförde effekterna av gruppbehandling med CBT (n=45) samt MMI (n=58) med effekterna av sedvanlig behandling (n=61) på sjukfrånvaro. Studie III undersökte sambanden mellan patientvariabler och livskvalitet genom en linjär regressionsmodell. I Studie IV gjordes samma analys som i Studie III avseende livskvalitet vid ettårsuppföljning och en jämförelse gjordes med effekten av behandling genom en linjär regressionsmodell. Livskvalitet mättes med summan av Mental Component Summary (MCS), Physical Component Summary (PCS) i korta versionen av 36 (SF-36).

en anställning, vara utrikesfödd (omvänd) och att ha en personlighetsstörning (omvänd) var starka prediktorer av livskvalitet vid ettårsuppföljning. Den starkaste prediktorn av MCS vid ettårsuppföljningen var gruppbehandlingen med MMI.

**Slutsatser:** Transdiagnostisk gruppbehandling ledd av undersköterskor kan vara effektiv för patienter med vanliga psykiska åkommor inom primärvården. En minskning av psykiska symtom och ett ökat välbefinnande verkar inte ha någon effekt på sjukfrånvaro. Depressiva syndrom och symtom var faktorerna med störst negativ påverkan på MCS hos primärvårdspatienter med mild till måttlig psykisk ohälsa före behandling. Ett år efter behandling så var personlighetssyndrom samt ångestsjukdom de starkaste negativa faktorerna. Faktorer med positiv påverkan var att ha ett arbete samt att vara född i Sverige. Starkast positiv effekt på livskvalitet var MMI behandling ett år efter behandling.
14 LEARNING AND OUTCOMES

I have gained new knowledge on a range of scientific issues. I have also learned how important psychological treatment is in order to support and to give care to all patients at the primary care center.
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