Vitality Training - a group-based intervention for persons with rheumatic diseases

Experiences, methodological aspects and clinical effects

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January 2012

Series of dissertations submitted to the
Faculty of Medicine, University of Oslo
No. 1374

ISBN 978-82-8264-284-2

Cover: Inger Sandved Anfinsen.
Printed in Norway: AIT Oslo AS.

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This is the material plane

And every outward thing we do is inner work

Coleman Barks

This we have now
is not imagination.

This is not grief,
or joy, not a judging state,
or an elation, or a sadness.

Those come and go.
This is the presence
that doesn't.

Jalaluddin Rumi (1207 -1273)

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Acknowledgements

Many persons have made this work possible, and each of them deserves a special thanks. First and foremost warm thanks to Eldri Steen, who introduced me to "Livsstyrketrening", initiated our first study and provided invaluable support and supervision throughout the whole process. Our many discussions during the last eleven years – about work and about life in general – have been very inspiring for me.

This thesis would not have been possible without highly competent support from my two supervisors, professor Kåre Birger Hagen and professor Arnstein Finset. I owe special thanks to Kåre Birger, who encouraged me to start working on this thesis. When I have hesitated along the way, he has always been there to encourage me and provide wise counselling. His friendly, but firm push has been necessary to complete the work. Arnstein has had the very special ability to see what was needed at key points to raise the quality of my work. His wise comments have always brought me a step further. Special thanks go to him also for introducing me to the highly competent work relationship at the Department of Behavioural Science.

I have been privileged to have very talented co-authors. Petter Mowinckel has been the statistical advisor for all the papers. Thanks go to Petter for taking time to listen to my many questions and patiently sharing his knowledge about, at times, sophisticated statistical procedures. Thanks also to Annette Stanton who generously gave me the possibility to translate and validate the Emotional Approach Coping Scale and to Andrew Garratt who skilfully guided me through the process of reporting the validation study. The qualitative analyses and article would not have been the same without the invaluable assistance from Mona-Iren Hauge. She widened and deepened my understanding of qualitative methods. I would also like to take this opportunity to thank Petter Andreas Steen, who have read, commented on and refined all my manuscripts, including the final theses.

Liv R. Eriksson, Turid Ø. Høystad and Anne Kristine Lunde are co-authors of paper IV. They deserve special thanks for having made this study possible. They believed in the project, recruited patients, arranged information meetings, aided with data collection and facilitated groups. I respect and admire them for always having the patients in focus and for their commitment to "Livsstyrketrening". A very special thanks goes to Liv for listening and sharing her thoughts and for always reminding me of how important this work is to the patients.

I also want to thank all the other group facilitators, who devoted their time and commitment to this project: Solveig Berre, Anlaug Brandslien, Ingvild Bø, Anne Dingsør, Inger Lise Grimsø, Tove B. Jensen, Aud Kjær, Aina Lium, Lindis Lokna, May Britt F. Lyngroth, Guro Mjønner, Marit Moen, Birgit S. Næss, Aud Rønningen, Dagheid Solholm, Bente Slungaard, Elin Skredtveit and Anne Tøvik. And many thanks to Ingvild Larsen-Asp for valuable secretarial help during the first study.

Thanks to Elfrid Flataker, Kristine Hagelund, Bente Hamnes, Hege S. Koksvik and Hanne Vestaby, who carried out the data collection for the validation study. Bente also contributed to translation of the EAC and she and I have collaborated in several other projects during the last years. I am looking forward to further collaboration when we both have finished our theses.

The present work has been carried out at National Resource Center for Rehabilitation in Rheumatology at Diakonhjemmet Hospital. I am very grateful for all my supportive,

encouraging and talented colleagues. Without them, this would have been a lonely journey. They have always been easy to ask whenever I needed their help. Special thanks to Aase Frich, Ylva Helland, Kristin Holstad, Mari Klokkerud, Ida Løchting, Solvår L. Reinsberg, Caroline Thorskog and Gerd Jenny Aanerud who conducted the telephone interviews. Aase has also provided valuable secretarial help and not least, a listening ear to all my worries and joys along the way. Several of my highly competent colleagues have read and commented on parts of my work. Warm thanks to all of them. I would also like to take this opportunity to express my gratitude to all my leaders, supervisors and colleagues at Diakonhjemmet Hospital, who have given me opportunities for meaningful work and development through my nearly thirty years as a nurse and for supporting the work with this thesis.

Finally, I want to thank all those who have first-hand knowledge about what it is like to live with a lifelong disease. It is these persons this thesis is really about. They deserve thanks for spending their time and effort not only in participating in the VTP, but also for answering questionnaires and sharing their experiences. They are our most important teachers. Thanks to Ann Brith Songe-Møller and Trond Halvorsen, whom Eldri and I collaborated with in the first phase of the project, and to Gro Demiri and Gerd Jenny Aanerud, who shared their thoughts and experiences in a later phase.

Last and most of all, I want to thank my friends and family for always being there for me through life's changing phases. You help me see my work in its proper perspective and to remain focused on what is most important in life. And most importantly, I want to thank my husband Siamak for love and care and for always keeping me in the present moment. My most precious moments in life are with you.

Summary

Background: During the last decades there has been a shift away from the traditional view of health care professionals as the only experts and providers of knowledge and the patients as passive recipients, to a more collaborative approach, recognizing the patient as an active agent in managing illness and own health care. Within the health care system, one has gained a broader understanding of the complex interaction between person and disease and realized that a narrow biomedical approach is inadequate. Although pharmacological treatment for patients with rheumatic diseases has developed remarkably, not all patients are eligible for the new medications, the disease process is still only partly controllable, and many patients need to make demanding lifestyle changes. There is therefore a need for non-pharmacological interventions that enhance individuals' coping abilities and help them to adjust to living with a lifelong disease.
The Vitality Training Programme (VTP) is a group intervention that aims at enhancing people's health promoting resources, their capacity to engage in the process of everyday living and ability to live a meaningful and valued life. Rather than focusing on strategies to control or reduce symptoms, the VTP explicitly emphasises the importance of non-judgemental attention to thoughts, feelings and bodily senses without attempting to avoid or change them. Beneficial effects have been documented in persons with chronic musculoskeletal pain, but the VTP has previously not been evaluated in persons with inflammatory rheumatic diseases.
Aims: The main aims of this research project were: 1) to evaluate effects of the VTP on psychological wellbeing, coping and disease-related symptoms in patients with chronic rheumatic diseases, 2) to explore participants' VTP experiences, and 3) to test the measurement properties of an instrument to measure emotion-focused coping, the Emotional Approach Coping Scale (EAC), in Norwegian patients with rheumatic diseases.
Materials and methods: First, persons with various inflammatory arthritides (IA) and fibromyalgia syndrome (FMS), who attended the VTP at six rheumatology departments, were included in a prospective pre – post-test study with one-year follow-up (n = 175). Participants in the first ten groups were also asked to take part in qualitative focus group interviews (n = 69). Second, the Emotional Approach Coping Scale (EAC) was translated to Norwegian and tested in three different samples, a consecutive sample of patients attending rheumatology clinics (n = 118), a sample of patients attending the VTP (n = 36), and a sample attending a self-management program at a rheumatology hospital (n = 66). All patients had confirmed rheumatologic diagnoses of at least 0.5 years duration. Validity was tested in a cross-sectional study including all three samples, whereas responsiveness was tested in the two intervention groups. Finally, persons with inflammatory rheumatic joint diseases were recruited to a randomised controlled trial and allocated to either the VTP (n = 36) or routine care control plus a CD with mindfulness-based home exercises (n = 35). Qualitative data, collected from the focus group interviews were analysed by a qualitative content approach (paper II). Quantitative data were collected by self-report questionnaires and analysed by a variety of statistical methods, including paired t-tests for within-group changes (papers I, and III), bivariate and multivariate regression analyses of predictions (paper I), principal component factor analysis and correlation statistics (paper III), and mixed models repeated measures analyses of between-group effects (paper IV). Effect sizes were estimated by standardised response mean (SRM) (paper I and III) and by Cohen's d statistic (paper IV).

Results: In the pre – post-test study, psychological distress, wellbeing, self-efficacy pain and symptoms and self-care ability were significantly improved in IA patients post-intervention, and the improvements were maintained at one-year follow-up (all p-values < 0.001). The SRMs ranged from 0.63 (wellbeing) to 0.41 (self-care ability). No significant reduction was found in fatigue after intervention, but at one-year follow-up fatigue was significantly reduced in IA patients (p = 0.007). No statistically significant improvements were found in any variables in patients with FMS. Inflammatory diagnosis and higher scores of fatigue at baseline were the main predictors of reduction in psychological distress at one-year follow-up.
Participants in the focus groups described how the VTP had helped them to recognize themselves as both ill and healthy, to recognize their emotions, and to become more aware of their own needs. Being part of a supportive community and being recognized as a credible patient had been important facilitators of their outcomes.
The EAC had low levels of missing data, and results from principal component analysis supported the two subscales, Emotional Processing and Emotional Expression, which both had high Cronbach's alphas of 0.92 and 0.90, respectively. Both EAC Processing and EAC Expression increased significantly in the VTP group after intervention (p-values < 0.05), whereas there were no significant changes in the EAC scales in the self-management sample at follow-up.
In the randomised controlled trial, significant treatment effects in favour of the VTP group were found post-treatment, and effects were maintained at 12 months in psychological distress (effect size 0.58), self-efficacy pain (effect size 0.59) and symptoms (effect size 0.92) and emotional processing (effect size 0.43). In the VTP group, the number of persons with serious psychological distress was reduced from 13 (36%) at baseline to 2 (6%) at 12 months compared with from 10 (29%) to 8 (24%) in the control group (p = 0.045). Significant treatment effects in favour of the VTP group were also found post-treatment and at 12 months in fatigue (effect size 0.50), self-care ability (effect size 0.59) and wellbeing (effect size 0.43). The improvement in fatigue was increased at 12 months in the VTP group, whereas the control group was unchanged from baseline. Effects in pain and the patient global assessment of disease activity did not reach statistical significance.
Conclusions and implications: This research project has illuminated how a process-oriented group intervention that focuses on topics related to life rather than the disease, explicitly addresses disease-related emotions and combines mindfulness-based and creative exercises, can enhance emotional wellbeing and strengthen individuals' belief in their abilities to manage their symptoms. Beneficial health effects were documented in terms of reduced psychological distress and fatigue. The EAC was found to be a valid and responsive instrument for measuring emotion-focused coping in persons with rheumatic diseases. These results show that the VTP is a feasible intervention that should be considered as a beneficial complement to existing treatment for patients with inflammatory rheumatic diseases, particularly for people who experience heightened psychological distress and fatigue.
Key-words: vitality, rheumatic diseases, psychological distress, fatigue, self-efficacy, coping, emotions, adjustment, mindfulness, qualitative research, repeated measurements, mixed models analysis

List of papers

Paper I: Zangi HA, Finset A, Steen E, Mowinkel P, KB Hagen The effects of a vitality training programme on psychological distress in patients with inflammatory rheumatic diseases and fibromyalgia: a 1-year follow-up. Scandinavian Journal of Rheumatology (2009), 38:3,231 - 232.

Paper II: Zangi HA, Hauge MI, Steen E, Finset A, Hagen KB "I am not only a disease, I am so much more". Patients with rheumatic diseases' experiences of an emotion-focused group intervention. Patient Education and Counceling (2011), 85: 419 - 424.

Paper III: Zangi HA, Garratt A, Hagen KB, Stanton AL, Mowinckel P, Finset A Emotion regulation in patients with rheumatic diseases: validity and responsiveness of the Emotional Approach Coping Scale (EAC). BMC Musculoskeletal Disorders (2009), 10:107.

Paper IV: Zangi HA, Mowinkel P, Finset A, Eriksson LR, Høystad TØ, Lunde AK, Hagen KB A mindfulness-based group intervention to reduce psychological distress and fatigue in patients with inflammatory rheumatic joint diseases: a randomised controlled trial Annals of the Rheumatic Diseases (2011), Dec 20 [E-pub ahead of print].

Abbreviations

AS	Ankylosing spondylitis
ASES	Arthritis Self-Efficacy scale
ASMP	Arthritis self-management program
BACQ	Brief approach/avoidance coping questionnaire
CD	Compact disc
CI	Confidence interval
CBT	Cognitive behavioural therapy
DMARD	Disease modifying anti-rheumatic drug
EAC	Emotional Approach Coping scale
ES	Effect size
EULAR	European League Against Rheumatism
FMS	Fibromyalgia syndrome
GHQ	General Health Questionnaire
HAQ	Health Assessment Questionnaire
IA	Inflammatory arthritis/arthritides
JIA	Juvenile ideopatic arthritis
MBCT	Mindfulness-based cognitive therapy
MBSR	Mindfulness-Based Stress Reduction
NRS	Numerical Rating Scales
OA	Osteoarthritis
PCA	Principal component analysis
PGA	Patient global disease activity
PsA	Psoriatic arthritis
QoL	Quality of life
RA	Rheumatoid arthritis
RCT	Randomised controlled trial
SD	Standard deviation
SLE	Systemic lupus erythematosus
SMP	Self-management program
SRM	Standardised response mean
VAS	Visual Analogue Scale
VTP	Vitality Training Program

1. Introduction

I have been working at the National Resource Center for Rehabilitation in Rheumatology (NRRK) at Diakonhjemmet Hospital since the centre was founded in 1999. During this period major changes have taken place in the field of rheumatology. One is the substantial advance in medical treatment that has improved quality of life for a large group of patients with inflammatory rheumatic diseases. Another is the increased focus on patient participation and inclusion of the patient perspective in individual health care, as well as in the overall health care system and research. There has been a shift from the traditional view of health care professionals as the only experts and providers of knowledge and patients as passive recipients, to a more collaborative approach, recognizing the patient as an active agent in managing illness and own health care. An increased understanding that a narrow biomedical approach is inadequate has evolved within the health care system (1-4). These changes have also led to a broader understanding of the complex interaction between person and disease. How people respond to their illness and experience their quality of life cannot be explained by the severity of the disease and symptoms alone, and existing medical treatments are not sufficient to cure or control all symptoms and disease processes (5;6). By listening to the patients we have learned that previous life experiences, personal identity, how the disease interferes with their current life situation, future hopes and wishes, how they perceive their abilities to cope with stressful events and what kind of social support they experience, have a great impact on how people adjust to living with chronic disease.

The Vitality Training Programme (VTP) is a group intervention that aims at enhancing people's health promoting resources, their capacity to engage in the process of everyday living and ability to live a meaningful and valued life. Rather than focusing on strategies to control or reduce symptoms, the VTP explicitly emphasises the importance of non-judgemental attention to thoughts, feelings and bodily senses without attempting to avoid or change them. Liv Haugli, an occupational medicine physician, and Eldri Steen, a nurse and health educator with

many years of counselling experience, developed the VTP in the late 1990s in close collaboration with people who lived with chronic musculoskeletal pain and health care professionals working with this group of people. The intervention was described and evaluated in a doctoral thesis (7).

When I learned about Steen and Haugli's work in 2000, I thought that the VTP might be a helpful intervention for people with inflammatory rheumatic diseases as well. I presumed that this kind of intervention would fill in a gap between existing medical and physical treatments for these patients, and the patients' needs for dealing with the emotional and social aspects of their chronic condition. Accordingly, a telephone contact with Eldri Steen initiated a ten-year collaboration of adapting, implementing and evaluating the VTP for persons with rheumatic diseases.

First, we adapted the VTP in collaboration with two persons who had long-term experience of living with inflammatory arthritis. Then we tested the program in two pilot groups and made further adaptations according to participants' responses. In parallel, group facilitators from six rheumatology departments were trained in a one-year educational program, and from January 2003 the VTP was implemented in six rheumatology departments. At the same time we started a pre – post-test study of clinical effects of the VTP in persons with rheumatic diseases. Based on the previous studies by Haugli and Steen (8-11), we did not consider the VTP to be a diagnosis-specific intervention. We therefore included a wide range of inflammatory and non-inflammatory rheumatologic diagnoses in our first study (papers I and II). On the basis of these results, we realised the need for evaluating the VTP in a less heterogeneous group. Consequently, we included only persons with inflammatory rheumatic joint diseases in the last study; a randomised controlled trial (RCT). Recognising the importance of including patient perspectives in developing and evaluating interventions, we also conducted a qualitative focus group study in order to illuminate experiences from VTP participation. The study also revealed a need for measuring emotion-focused coping. We therefore translated and tested the properties

of an instrument called the Emotional Approach Coping Scale (EAC) in Norwegian patients with rheumatic diseases.

The present thesis comprises the qualitative study of experiences from VTP participation, the methodological study of EAC measurement properties and the evaluation of clinical effects of the VTP in persons with chronic rheumatic diseases.

2. Background

2.1 Rheumatic diseases

Rheumatic diseases include diseases and painful conditions in the joints and musculoskeletal system and the connective tissues. They can be categorised into four main groups: 1) inflammatory rheumatic joint diseases, 2) systemic rheumatic diseases, 3) osteoarthritis and 4) local and generalised pain conditions (for example fibromyalgia syndrome) (12). The main groups of diagnoses included in this thesis are inflammatory rheumatic joint diseases and fibromyalgia syndrome. These diagnoses will therefore be further described.

2.1.1 Inflammatory rheumatic joint diseases

The inflammatory rheumatic joint diseases include the diagnoses rheumatoid arthritis (RA), juvenile ideopatic arthritis (JIA), ankylosing spondylitis (AS), psoriatic arthritis (PsA), and inflammatory bowel diseases-related arthritis. RA affects approximately 0.5 – 1% of the northern European and North American populations (13;14), AS approximately 0.1 - 0.2% (15;16) and PsA approximately 0.2 - 1% (17;18). RA affects more women than men with a ratio between 4:1 and 5:1 below the age of 50 and 3:1 above the age of 50 (13). AS affects more men than women with a ratio of between 3:1 to 2:1 (15;16), and PsA has an equal gender frequency (19). Although the pathogeneses of the diseases differ between, as well as within the diagnostic groups, they all have a systemic inflammatory component considered to be of an autoimmune nature (14). The inflammatory process causes various degrees of joint destructions, pain, swelling and stiffness. RA may affect almost all joints, but particularly hands, wrists and feet (14), whereas AS typically affects spinal joints (15;16) and PsA may involve both large joints and the spine. PsA is also associated with skin-related physical effects; psoriasis (18;19).

The inflammatory rheumatic joint diseases have great impact on all aspects of life. In addition to joint affections, the disease-induced inflammatory process can mediate more general physiological and psychological symptoms. Among other factors the autoimmune reaction involves pro-inflammatory cytokines (e.g. TNF-α, interleukin 1 and interleukin 6). These cytokines seem to promote a constellation of non-specific responses, such as vital exhaustion with loss of energy, inability to concentrate, increased irritability, depressed mood, decreased activity and reduced appetite, which are normal reactions when the human organism fights acute infection. This constellation of symptoms, referred to as 'sickness behaviour' (6;20), may also be experienced by people with chronic inflammation, and may be one of the mechanisms associated with fatigue in inflammatory rheumatic diseases (21).

Patients with RA frequently report pain as their most disabling symptom (22;23) and have ranked pain as the most important symptom to be improved (24). There has also been an increasing awareness of the significance of fatigue in persons with inflammatory arthritis (IA), and fatigue is considered a major obstacle to optimal function (25) with an impact similar to pain (19;26-33). Moreover, several studies have shown that inflammatory rheumatic diseases are associated with impaired functional ability, reduced emotional wellbeing, and loss of social activities (19;22;23;32;34-37). The relationship between disease activity and its physical and psychosocial impact is not one-dimensional. There seem to be a complex interplay between biological, psychological and social factors (5;38).

During the last decade, RA treatment has changed remarkably. The progress in understanding the pathogenesis has led to development of biological therapies and better targeted use of traditional disease-modifying anti-rheumatic drugs (DMARDs). These changes have resulted in substantial improvements in many patients' quality of life (QoL) (14;39;40). In later years, these therapies have also become available for patients with AS and PsA (41-46). However, the treatment strategies are more effective in patients with recent onset than in patients with established disease, and

not all patients are eligible for the new medications. Thus, for several patients, the disease process is still only partly controllable (39;47).

In addition to the pharmacological treatment, there is considerable evidence for the beneficial effects of physical training in patients with RA and AS. Currently, there is an agreement that physical activity enhances fitness, muscle strength and functional ability, without negative effects on disease activity (48;49). There is also evidence that physical exercise inhibits production of pro-inflammatory cytokines and is associated with improved emotional status in patients with RA. The physical training should be individually designed and initially be supervised by a physiotherapist (50).

2.1.2 Fibromyalgia syndrome

Fibromyalgia syndrome (FMS) is characterised by chronic widespread pain and a range of other symptoms, such as fatigue, sleep disturbance, functional impairments, stiffness, depression, anxiety and irritable bowel syndrome (51-53). Pain and fatigue are most frequent and disabling, and the reported levels of these symptoms are generally higher than in patients with IA (54). FMS varies in severity, but most patients report reduced QoL and difficulty with routine daily activities, and 30 to 40% have to stop work or change employment (55). Physical function is usually impaired and mental health scores are reduced compared to both normal healthy controls and other rheumatic diseases, such as RA and osteoarthritis (OA) (54;56). Furthermore, persons with FMS often experience disbelief about their condition, negative social responses and lack of understanding from family, colleagues and health care professionals (57).

Because of the complexity of the FMS and the variety of symptoms, it is recommended that the treatment should be tailored to the individual's needs and most distressing symptoms. A multidisciplinary approach, combining pharmacological and non-pharmacological interventions is found to be the best option. Pharmacological treatment includes analgesics and tricyclic antidepressants. Non-pharmacological

treatments include patient education, aerobic exercise, strength training and cognitive behavioural therapy (CBT) (53;58).

2.2 Living with a lifelong disease: Adjustment and coping

Living with a chronic rheumatic disease has the potential to induce profound changes in people's lives. The diseases often fluctuate with symptoms varying from day to day or over longer periods of time, and the long-term consequences are unpredictable. These potentially stressful experiences will naturally evoke emotional reactions and may affect the person's psychological health (5;6;38). Moreover, the need for long-term medical treatment combined with a demand for life-style changes will challenge a person's habitual coping strategies. How people cope with disease-induced stress and adjust to the changes can influence their emotional wellbeing, vitality, life satisfaction, global self-esteem, social interactions and overall QoL (6). Previously, research focused mainly on why people failed to achieve healthy adjustment, while there currently is a greater emphasis on understanding how adjustment is promoted (6;59-61). A wide range of educational and psychosocial interventions has been designed to enhance individuals' coping abilities and facilitate their adjustment to the illness.

2.2.1 Stress, psychological distress and adjustment

'Stress' is a widely used term to describe a process in which an individual is exposed to a stressor and reacts with a series of stress responses. A stressor may take many forms. It may be a demand (e.g. expectations from self or others), an unmet need (e.g. personal goal commitments), a symptom (e.g. pain or fatigue) or an event (e.g. disease onset or disease impact per se) (62). Responses to stress include biological stress responses (e.g. hormonal responses), cognitive assessment of the stressor and behavioural responses. The diversity of biological stress responses will not be discussed in this thesis.

The experience of distress occurs when an individual perceives the stressor as a personal threat, which he/she is unable to control or cope with. The concept 'psychological distress' describes "the unique discomforting, emotional state, which an individual experiences in response to a specific stressor that results in harm, either temporary or permanent" (62). It may be an already encountered harm (e.g. functional limitations) or an anticipated threat (e.g. loss of work). Individuals who are distressed may verbally or non-verbally express feelings of discomfort, and they may experience changes in their emotional status towards depressed mood, de-motivation, irritability, aggressiveness and self-depreciation (63).

In clinical research psychological distress has often been assessed as symptoms of anxiety and depressed mood. Several studies have documented a high degree of psychological distress in patients with various rheumatic diseases (5;22;34;64-67). The prevalence of major depressive symptoms in persons with RA is higher than in healthy controls, varying between 13 and 25%, and persons with FMS are reported to be even more depressed (68). Persons with RA also exhibit higher levels of anxiety compared with a normative sample, and the gap is greater if the RA is combined with depression (23;69). These studies show that many of the factors known to be associated with the development of psychological disorders in the absence of physical illness are also relevant to the development of psychological problems in people living with chronic illness (60). Studies of persons with RA have shown that psychological distress is not predicted by the disease activity per se (70). In early stages of the disease, it is associated with pain level, disease impact on functional status and self-care, life events and perceived social support. In later phases, personal coping resources appear to become more important predictors of distress (70-72).

Adjustment refers to the patients' healthy rebalancing to their new circumstances and is a process that occurs over time. It begins at the presentation of symptoms and continues throughout the course of the illness (6;60). The process includes cognitive, emotional and behavioural responses and is influenced by individual coping strategies. A considerable number of patients seem able to adjust to illness without

experiencing clinically significant psychological problems. Nevertheless, the prevalence of psychological distress among persons with rheumatic diseases indicates a need for interventions, which are targeted at strengthening individuals' belief in their ability to cope with disease-induced stressors, provide opportunities for developing appropriate coping strategies and enhance adjustment to the disease.

2.2.2 Coping with Stress

Coping has to do with the way people manage life conditions that are stressful (73). Lazarus and Folkman distinguished between two main coping strategies: problem-focused coping aimed at changing the situation that causes distress, and emotion-focused coping aimed at changing the emotions caused by the stressful event (73;74). Two other widely used distinctions differentiate between approach-oriented and avoidance-oriented coping, or between passive and active coping strategies (75). All three dimensions have been used when studying adjustment to chronic illness, and there is no consensus among researchers about which distinction should be preferred in studies (76). Empirical evidence has shown that problem-focused or approach-oriented strategies are most applicable in situations that can be controlled, whereas situations beyond control are better dealt with in an emotion-focused approach (76;77). Studies in patients with RA has shown that depressed patients are more likely to use avoidance-oriented and passive coping strategies (78;79), and that the use of such strategies is a mediator of physical disability, pain and depression (80;81) and predicts poorer adjustment over time (59).

Previously, researchers studying stress and coping seemed to agree that emotion-focused coping processes were passive and avoidance-oriented, and associated with maladaptive health-related outcomes (6;82;83). It has more recently been documented that a broad coping repertoire, consisting of both problem-focused and emotion-focused strategies, increases the possibility of matching the response to the particular demands of a stressful situation, and therefore may be considered indicators of

effective coping (73;76). Based on newer understanding, emotion-focused coping strategies are no longer considered as only passive or avoidance-oriented (73;82;83).

2.2.3 Self-efficacy

The concept of self-efficacy has its origin in social cognitive theory and is defined as an individual's *personal confidence or belief* about his or her ability and capacity to undertake behaviours that will lead to desired outcomes (84-86). It has to do with the power people believe they have to make things happen and consequently their perceptions of control (84). The degree of perceived efficacy involves three separate, but interrelated conceptual domains: a) having tacit task knowledge and skills, b) having an explicit sense of confidence in one's ability to mobilize the motivation and cognitive resources required to perform a skill, and c) having confidence in one's ability to successfully execute a specific task or skill in a given context (86). Self-efficacy believes are behaviour-specific and a person's level of self-efficacy may therefore differ for various behaviours. Perceived self-efficacy can influence a person's motivation and attitude regarding behavioural change, emotions and coping attempts (5;86-88). The American nurse and researcher, Kate Lorig, had through her studies of patient education, observed that although knowledge might be necessary, it is not sufficient for changing behaviour. She was the first to apply the concept of self-efficacy in the context of rheumatology, showing that without the confidence to actually perform a needed activity, one will not achieve the desired outcome (85). Thus, self-efficacy is considered an essential component of individuals' management of their disease. Self-efficacy beliefs are found to be modifiable, and the concept is frequently used as an outcome measure in psychological and self-management interventions (85;86;88;89). Brekke and colleagues have documented associations between high self-efficacy and favourable changes in health status in a Norwegian cohort of RA patients (90).

2.2.4 Emotions and emotion regulation

There has been an increasing recognition of the role of emotions in adjustment to chronic illness. Persons living with chronic rheumatic diseases have to adjust emotionally to the consequences of the disease, and the way they regulate their emotions may affect their psychological wellbeing as well as other aspects of perceived health (6;82;83). Emotions arise when something important to us is at stake and call forth "a coordinated set of behavioural, affective and physiological response tendencies that together influence how we respond to perceived challenges and opportunities" (91). Although emotions trigger ways we respond to a situation, they do not force us to respond in certain ways. Emotional responses may be modulated and regulated in various ways. Emotion regulation refers to the conscious or unconscious processes by which individuals influence which emotions they have, when they have them and how they experience and express their emotions (91-93). Gross (91) distinguishes between two emotion regulation strategies, *antecedent-focused* strategies, i.e. things we do before the emotional response tendencies have become fully activated and *response-focused* strategies, i.e. things we do after response tendencies have been generated. How emotions are experienced and expressed may have important implications for adjustment to illness. Van Middendorp and colleagues (94) describe four styles of emotion regulation: 1) *Ambiguity*, which is difficulty in identifying and describing emotions and ambivalence of expressing emotions, 2) *Control*, which is more or less intentionally keeping feelings inside, trying to restrain feelings and be rational when emotions are experienced, 3) *Orientation*, which is being emotionally oriented and experiencing emotions intensely, and 4) *Expression* of negative and positive emotions towards others.

There is a growing consensus that emotion regulation in terms of acknowledging and expressing emotions associated with chronic illness can promote healthy adjustment. Experimental studies in persons with RA and other chronic pain conditions has demonstrated beneficial effects on global disease activity and psychological

functioning of emotional disclosure interventions, i.e. talking or writing about emotions in stressful experiences (95-99).

2.2.4.1 Coping through emotional approach: Active processing and expression of emotions

Based on the concepts from stress and coping theory (74), Stanton and colleagues demonstrated that there is a type of emotion-focused coping that appears to be adaptive rather than maladaptive (83;100;101). They suggested that the reason for the erroneous conclusion that emotion-focused coping is associated with maladaptive outcomes and psychological distress, is the way it has been operationalised in earlier coping measures. Diverse coping strategies, such as approach-oriented (for example "I learn to live with it") as well as avoidance-oriented (for example "I say to myself that this isn't real") have been assessed as emotion-focused coping. Moreover, emotion-focused coping-scales have included both items related to acknowledgement of emotions (for example ""I let my feelings out") and items related to emotional distress (for example "I blame myself for becoming too emotional"). Some of these items are inversely correlated. Consequently, the scales are not purely assessing psychological adjustment, but are mixed with aspects of psychological distress (83;100;101). In contrast, Stanton and colleagues argue that the ability to approach own and others' emotions is crucial to healthy intra- and interpersonal functioning, and they have developed a construct labelled C*oping through emotional approach*, intending to measure the adaptive functions of identifying, acknowledging and expressing emotions (101). They developed and validated a new instrument, the Emotional Approach Coping Scale (EAC), comprising two distinct factors: *Emotional Processing*, which includes active attempts to acknowledge, explore meanings and come to an understanding of one's emotions; and *Emotional Expression*, which includes active verbal and/or nonverbal attempts to communicate or symbolise one's emotional experience. These two factors were found to be related to other approach-oriented coping strategies, but uncorrelated with avoidance-oriented strategies. The EAC has been validated and used in a wide range of populations, including breast cancer and chronic pain patients (102-106).

Stanton and colleagues have suggested some working mechanisms of emotional processing and expression that contributes to the beneficial health effects: Acknowledging and seeking to understand emotions may clarify situations and call one's attention to important goals. Emotional processing may promote reappraisal of stressors, reduce perceived threat, and help individuals to find benefit in their experiences, which in turn may promote positive adjustment. Emotional expression may promote habituation to the stressor and aid in regulating individuals' social environment by providing information to others about their concerns and thereby affecting their responses (101).

2.2.5 Interventions designed to enhance adjustment and coping

The change towards a more collaborative approach between health care professionals and persons with rheumatic diseases is reflected in the design of interventions aimed at enhancing adjustment and coping. There has been a shift away from a primarily didactic education, providing the patients with knowledge to comply with prescribed treatment, towards a more participatory education aimed at empowering patients with skills and knowledge to manage their illness (1-4). Health care professionals are no longer the only experts; the patients have their own knowledge that health care professionals should understand in order to facilitate individuals' adjustment to their condition (1). The interventions are often referred to as psycho-educational or psychosocial, and they include, to various degrees, training of cognitive, emotional and behavioural coping skills.

Although there is some overlap between the various interventions, they also differ with regard to theoretical foundations, specific aims and methods. In the following I will describe the groups of interventions that are most commonly applied in persons with rheumatic diseases. The main results from selected evaluations of these interventions are summarised in table 1.

2.2.5.1 Self-management interventions

Self-management is defined as "the individual's ability to manage symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition" (107). The main aim of self-management programs (SMP) has been to involve patients in the management of their care in order to improve their ability to maintain physical function and to cope with the psychological demands of living with a chronic illness (89;107;108). The Arthritis Self-Management Program (ASMP), which was developed by Kate Lorig and colleagues at Stanford University, California, US from the 1980s, has become widely spread in North America, Europe and Australia. Although they may vary in content, enhancing self-efficacy by teaching skills, such as problem solving, goal setting, reinterpretation of symptoms, role modelling and mastery experiences are incorporated in most of the programs (86;109). In Norway, the ASMP has been adjusted to several chronic conditions and is known by the name "To live a healthier life" ("Å leve et friskere liv", www.funkis.no) (110).

The effects of the SMPs have been evaluated in several controlled trials and the results are summarised in a number of reviews (89;107;109;111). A range of beneficial short-term outcomes are documented, such as improvements in pain and fatigue, disability and psychological health, especially if a behavioural component is included (111-113) (Table 1). Lorig et al (114) have also showed that both baseline self-efficacy and changes in self-efficacy are associated with future health status. However, most outcome effects are generally found to be small, and there is a gap between short-term and long-term effects (88;115-117) (Table 1). A proposed explanation for this gap is that patients find self-management strategies burdensome and difficult to integrate into their lives and that they do not always experience immediate benefits in terms of symptom improvement (6).

2.2.5.2 Cognitive-behavioural interventions

Cognitive behavioural therapy (CBT) includes a range of strategies aiming to facilitate a realistic, but optimistic attitude towards illness and/or more adaptive

strategies to cope with symptoms (60). CBT is based on the notion that behavioural and emotional responses are strongly moderated and influenced by cognitions and the perception of events. As the name indicates, the interventions focus on cognitive processes although they are not limited to modification of thoughts. Hofmann and Asmundson (118) have categorised CBT techniques as primarily *antecedent-focused* emotion regulation strategies, i.e. they encourage cognitive reappraisal of emotional triggers before they occur or before the emotional response has been fully activated (91).

CBT is a problem-solving process that includes clarifying the status of the presenting problem, defining a desired goal, and finding the means to reach that goal. Patients are considered to be experts on their own problems. The therapist role is to work with the patient to find adaptive solutions to resolvable problems by identifying negative automatic thoughts and dysfunctional or irrational beliefs. These thoughts and beliefs are treated as hypotheses, which the patients are encouraged to challenge by putting themselves in the role of observers rather than being victims of their concerns. By confronting themselves with stimuli that provoke negative emotions, they have the opportunity to test the validity of their assumptions (118).

Group interventions based on CBT are often multi-modal. In addition to the cognitive strategies, education about the illness, goal setting and activity pacing, relaxation strategies, communication skills and management of flare-ups are included (60). Some studies on CBT in patients with rheumatic diseases have documented favourable effects in psychological health as well as coping and fatigue, especially when the intervention is given early in the course of the illness and when it is tailored to patients with a psychosocial risk-profile (113;119-123). One study in patients with RA and major depression did not find CBT additive to antidepressant medication (124) (Table 1).

2.2.5.3 Mindfulness and acceptance-based approaches

More recently some new approaches categorised as mindfulness- and acceptance-based therapies have received increasing attention (125). One of the core aspects in these therapies is training in open-hearted moment-to-moment awareness to internal experiences, such as thoughts, feelings and bodily senses without judging or wishing things to be otherwise, conceptualised as *mindfulness* (126). Another aspect of these approaches is the cultivation of *self-compassion*, i.e. kindness and care toward own experiences, seeing any thoughts, feelings and sensations that arise as part of the human experience rather than a sign of pathology, weaknesses or limitations (125). It is believed that experiencing the present moment non-judgementally, openly and reflectively can effectively counter the effects of stressors, whereas excessive orientation toward the past or the future when dealing with stressors, can be related to feelings of depression and anxiety (127;128). Acceptance is perceived to be the strongest mediator of human change and development. It is believed that if we can observe our thoughts and feelings by friendly accept without responding reflexively, we may gradually free ourselves from being controlled by automatic thoughts. In contrast to the CBT interventions, mindfulness- and acceptance-based approaches are categorised as *response-focused* emotion regulation, i.e. how we respond to emotions after they have been generated (91;118).

The mindfulness-based interventions have their roots in ancient Buddhist practices of meditation and yoga, and have been adapted and described in western secular terminology by dr. Jon Kabat-Zinn at Massachusetts General Hospital, Boston, US (126). Kabat-Zinn developed a program known as Mindfulness-Based Stress Reduction (MBSR), which over time has become widely implemented in western countries, including Norway (129-131). The beneficial effects of MBSR on depression, anxiety and stress-related symptoms have recently been documented in a number of reviews (127;132;133). So far, there are only few studies on mindfulness-based interventions in persons with rheumatic diseases, but these studies have shown significant effects of the MBSR in persons with RA and FMS (134-136) (Table 1).

Training of mindfulness-based practice has also been integrated in interventions with roots in cognitive behavioural therapy, such as Acceptance and Commitment Therapy (ACT) (137) and Mindfulness-Based Cognitive Therapy (MBCT) (138;139). The ACT has, in addition to the acceptance and mindfulness strategies, explicit focus on enhancing individuals' ability to live a meaningful and valued life, in which unpleasant emotions no longer serve as an obstruction. The aim is to develop larger and larger patterns of effective action linked to chosen values in various domains, such as family, career and spirituality, referred to as committed action (118;137;140). The effects of the ACT has been evaluated in studies of patients with chronic pain conditions, and favourable effects have been found in pain, coping and psychological health (136;141). To my knowledge there are no published studies of ACT in persons with IA.

The MBCT combines mindfulness-based training with cognitive strategies for identifying negative automatic thoughts and dysfunctional or irrational beliefs and view thoughts and feelings from a decentred perspective (metacognitive awareness) (142). Although trying to change negative thoughts and feelings seems to be contrary to the acceptance- and mindfulness-based approaches, there is some evidence that integrating mindfulness training into traditional CBT can decrease depressive symptoms (138;139). However, to date there are to my knowledge no publications of MBCT in persons with rheumatic diseases or chronic pain conditions.

Table 1: Overview of SMP, CBT and mindfulness-based studies in patients with rheumatic diseases

Study (Year)	Study design	Patients	Intervention	Follow-up time	Outcomes	Effects at follow-up (pooled effect sizes in reviews and meta-analyses)
Barlow JH et al (2000)(112)	RCT (n = 544)	Arthritis	ASMP vs. waitlist control in community health care	12 months	ASES sympt ASES pain Pain Fatigue Mood*	ES 0.39† ES 0.35† ES 0.18† ES 0.22† ES 0.33†
Riemsma RP et al (2003,2004) (111;116)	Systematic review (Cochrane) of RCTs (31 studies included)	RA	Patient education (various interventions including counselling and behavioural treatment)	2 – 4 months	Pain Disability Mood* Depression	ES 0.13 (ns) ES 0.12 (ns) ES 0 ES 0.14 (ns) Programs including a behavioural component showed best effects
Astin JA et al (2002)(119)	Meta-analysis of RCTs (25 studies included)	RA	Psychological interventions (CBT, multi-modal programs)	Average 8.5 months	Pain Disability Mood* Self-efficacy	ES 0.06 (6 studies) (ns) ES 0.12 (7 studies) (ns) ES 0.33 (5 studies) † ES 0.20 (3 studies) (ns) Interventions most effective for patients with shorter disease duration
Sharpe L et al (2001, 2003) (120;121)	RCT (n = 53)	RA (< 2 years disease duration)	CBT vs. routine care control	6 months and 18 months	Depression Anxiety Coping Pain Disability	p = 0.05 (6 m), 0.02 (18 m)§ p = 0.08 (6 m), 0.02 (18 m)§ p = 0.03 (6 m), P = 0.4 (18 m)§ ns (6 ms), P = 0.12 (18 m)§ ns (6 ms), P = 0.03 (18 m)§

Table 1, continued

Study (Year)	Study design	Patients	Intervention	Follow-up time	Outcomes	Effects at follow-up (pooled effect sizes in reviews and meta-analyses)
Evers et al (2002)(122)	RCT (n = 64)	RA < 8 years disease duration + psychosocial risk profile	CBT vs. routine control	6 months	Depression Pain Fatigue Mood*	ES 0.55† ns ES 0.48† ES 0.43†
Van Koulil et al (2007)(123)	Review of RCTs (30 studies included)	FMS	CBT/relaxation and/or exercise	3 - 15 months	Pain Disability Mood*	6 studies of multi-modal programs showed small effects at follow-up. Best effects on highly distressed patients.
Hewlett S et al (2011)(113)	RCT (n = 127)	RA	CBT for fatigue management vs. fatigue information alone	18 weeks	Fatigue Disability Depression Self-efficacy	p = < 0.01, ES 0.59 p = 0.03 p = < 0.01 p = 0.04
Pradhan EK et al (2007)(134)	RCT (n = 63)	RA	MBSR vs. waitlist control	6 months	Distress Depression Wellbeing	p = 0.04 p = 0.08 p = 0.03 (All values are between-group effects)
Sephton SE et al (2007)(135)	RCT (n = 90)	FMS	MBSR vs. Waitlist control	2 months	Depression/ Anxiety	p = 0.002, ES 0.11
Veehof MM et al (2011)(136)	Systematic review and meta-analysis (14 controlled trials included)	Chronic pain (RA, FMS, other pain syndromes)	Acceptance-based interventions (MBSR and ACT)		Pain Depression Anxiety Physical wellbeing	SMD 0.37† SMD 0.32† SMD 0.40† SMD 0.35†

Various measures of psychological health included, ES = Effect size, † P-value < 0.05, ns = non-significant, §values are between-group effects,
RCT = randomised controlled trial, RA = rheumatoid arthritis, FMS = fibromyalgia syndrome
ASMP = Arthritis Self Management Program, CBT = Cognitive Behavioural Therapy, MBSR = Mindfulness-based Stress Reduction
ACT = Acceptance and Commitment Therapy

2.3 The Vitality Training Program (VTP)

The name of the intervention, Vitality Training, needs some explanation. The Norwegian name is 'Livsstyrketrening', which directly translated means “training of life strength”, and covers the purpose and the content of the intervention and the process that the participants experience throughout the program. The name was first proposed by the anthropologist Hans Einar Hem, who as a participant observer evaluated the intervention on behalf of the Norwegian Ministry of Health and Care Services in 1997. To find an English concept synonymous to 'livsstyrke', we contacted the Department of English Language Studies at the University of Oslo and the concept 'vitality' was proposed. Vitality is defined as “(full of) energy and enthusiasm” (Oxford Advanced Learner's Dictionary 2005), “capacity to live and develop; physical or mental vigour especially when highly developed” (Free Merriam-Webster Dictionary), “exuberant physical strength or mental vigour; capacity for survival or for the continuation of a meaningful or purposeful existence; power to live or grow” (Dictionary.com). These meanings correspond well with the intentions behind the Norwegian name 'Livsstyrketrening' and the purpose and content of the intervention, and the name 'Vitality Training' was therefore selected.

The VTP was originally developed for persons with chronic musculoskeletal pain. The design of the VTP was driven by the authors' (Eldri Steen and Liv Haugli) pragmatic motivation to create a meaningful, feasible and effective intervention and by their clinical experience with participation-based teaching and counselling methods. The main aim was to develop an intervention that could help people with chronic musculoskeletal pain to cope in more constructive ways with their symptoms and life challenges (143). Some theoretical assumptions directed the development of the programme.

2.3.1 Theoretical background and main concepts

Although Norwegian patients in the 1990s were engaged in promotion of their health and to a certain extent involved in decisions regarding their illness, the biomedical model was still prevailing in medical care. In this model the body was understood as an object and bodily phenomena were considered as symptoms to be diagnosed and behaviours to be modified (144). Pain and other symptoms were mainly understood as either physical with an identifiable cause, or psychological with unclear or unidentifiable causes. Health care professionals were very much the experts who owned the knowledge and could decide what was the right and best for any patient regardless of his/her preferences. Steen and Haugli proposed a contrasting, phenomenological view of the person, in which the human body is considered as a subject and carrier of experience and meaning. Thus, bodily phenomena cannot be understood as isolated events, but must be viewed in the context of the whole person (144). Their main assumptions were: 1) Individuals interpret situations and symptoms in multifaceted ways and construct their own meanings of the situations they are in, and they have the capacity to reinterpret situations and construct new meanings when needed. 2) The impact and meaning of living with a chronic condition can only be understood by addressing an individual's own experience-based knowledge. This implies that interventions should provide opportunities for the participants to find their own meaningful ways of coping with and adjusting to the disease (143).

2.3.1.1 Consequences for teaching and learning

These assumptions resulted in some basic principles for how the intervention should be designed (143). The programme should:

- enhance awareness of the present moment, i.e. pay attention to thoughts, feelings and bodily senses as they arise moment-by-moment, without attempting to avoid, analyse or judge them
- enhance awareness of the relationship between inner experiences (senses, thoughts, feelings), interpretation of these experiences and behavioural patterns

- enhance awareness of personal resources and possibilities rather than symptoms and limitations
- involve cognitive, emotional and behavioural learning processes
- create learning situations, in which participants are allowed to relate and respond actively to any issues and topics addressed
- facilitate learning as an individual discovery process that cannot be forced

The theoretical foundation for the learning processes and methods was inspired by gestalt psychology and principles of confluent education (145-148). Gestalt psychology is concerned with how and what we perceive, and how we construct meaning. Fundamental goals are to complete unfinished situations from the past that are obstacles to health, wholeness and good contact with oneself and others, and to develop the capacity and skills to engage authentically, responsibly and satisfactory in the process of everyday living (145). 'Confluent education' is a theory of learning derived from gestalt psychology that aims at integrating emotional, cognitive and behavioural processes in learning (146-148). Learning is an experience-based process that occurs in a dialectic relationship between participant, group facilitator (the 'teacher'), content and environment. Although developed from different theoretical backgrounds, the VTP has many common features with the mindfulness- and acceptance-based approaches described in section 2.2.5.3. An underlying belief in interventions derived from these approaches, as well as in the VTP, is that increased awareness may enable persons to reduce their automatic behaviour responses and strengthen their ability to make more conscious choices about how they respond to experiences.

2.3.1.2 Essential concepts in the VTP

Awareness is how we get in touch with our experiences and access the world through our senses, i.e. what we see, hear, smell, taste and feel. Awareness makes options and choices possible, instead of automatic and unconscious reactions. Awareness opens up for contact with emotions and unfinished situations that hinder movement and growth.

Here-and-now focus: Now is the time to be aware of and pay attention to what is actual moment-by-moment, now is when we experience feelings and make choices, and now is the only time we have the power to influence an event, for events happen only in the moment.

The paradoxical nature of change: The VTP is not targeted toward changing the individual. Change is desired, but we do not force change to come about by having a predefined goal. It is not known what this change will be. Paradoxically, change takes place when a person stops trying and accepts what *is* (146;149).

These three concepts are analogues to the basic principles of awareness of the present moment and the processes of non-judgemental attention to whatever arises, internally or externally, that we find in the mindfulness and acceptance-based approaches. In addition, the VTP focuses on the *content* of what the person becomes aware of. The participant's experiences, thoughts, feelings and physical reactions are gateways to discovering, making explicit, and facilitating the learning processes. The focus is always on what the person becomes aware of in the present moment. However, feelings and sensations here and now may have their sources in unfinished situations from the past, and uncompleted experiences make it difficult to be present *now* because we are partly in the past. Until these feelings are recognised and understood they may be obstacles to further growth and development. In the VTP, various creative methods, such as guided imagery, movement to music, using crayons and white papers to express internal images, poetry and metaphors, are used in combination with awareness exercises. The purpose of these methods is to provide opportunities for the participants to express thoughts and emotions non-verbally and verbally, complete unfinished situations and discover more of whom they are and what they need.

Furthermore, *contact* is an essential element, i.e. the meeting of myself and what is different from myself - other people and things in the environment. Contact assumes acknowledgement of own and others' existences as separate beings. Through contact, people grow and change. This is never a purely cognitive process, but can include

awareness and acknowledgement of our inner experience, such as feelings associated with the contact. Contact provides the possibility for relationship with others and the potential for process, energy, dialog, and new meanings (145).

Finally, the VTP is targeted at increasing attention of what is important to the individual and strengthen his/her ability to make choices in accordance with their own *values* instead of expectations from others or what they think is socially acceptable. This process is analogous to the values-based action described in the ACT (137).

2.3.1.3 Consequences for education of group facilitators

The group facilitators' own inner and outer awareness is essential. They have to possess the skills of being present, paying attention, seeing and hearing the participants as they present themselves, and to respond to them human-to-human (8;145). They are therefore trained in confluent methods and delivery of the VTP before they are approved as group facilitators. The training comprises six three-day workshops over one year, plus home assignments and a practical examination at the end of the training. Activity, participation, discoveries and reflection on own experiences are central elements in the training. By practicing and getting feed-back they experience the different methods both as group participants and as facilitators, including the importance of respect, trust and acceptance (8).

The group facilitators are health care professionals, such as nurses, occupational therapists, physiotherapists and social workers, who by their professional education typically are trained to be ‘experts’ and give advices. In contrast, through confluent education they learn not to present the ‘right answers’, but to help individuals explore and discover their personal resources and values and to find their own meaningful solutions (150).

2.3.2 Effects of the VTP in persons with chronic musculoskeletal pain

Haugli and Steen evaluated VTP effects in a randomised controlled trial (RCT) for persons with chronic musculoskeletal pain, such as fibromyalgia, neck and shoulder syndromes and low back pain, (9-11). They found significantly reduced psychological distress in the VTP group compared to the controls after the intervention and at one-year follow-up ($p < 0.001$). The differences between groups were slightly reduced at one year follow-up, but still significant ($p < 0.05$) (11). The VTP group also reported significantly reduced pain ($p = 0.02$) and increased pain coping and self-care ability compared to the controls at one-year follow-up (p - values 0.010 and 0.02, respectively) (10). Persons with high 'agency-orientation', i.e. those who tends to perceive themselves as originators of behaviours, benefited more from the program in terms of higher coping ability and self-care ability than persons with low 'agency-orientation' (p - values < 0.05) (9). The authors also conducted a qualitative study, using open-ended questions in self-report questionnaires immediately after and one year after the intervention. Analyses of participants' written texts showed that they had gained increased awareness of the complex relations between their bodily symptoms, thoughts, feelings and their current life situation. They had also increased their awareness of own resources and possibilities as opposed to focusing on diagnoses. The VTP had provided a room for experimenting, for experiencing community and for acceptance of self and others. The group facilitators' abilities to act as human-to-human and to focus on self-discovery rather than symptoms, had been important (8).

2.3.3 The rationale for the present study

Based on the described needs for interventions that enhance adjustment and coping resources in persons with chronic rheumatic diseases and the lack of such interventions in the Norwegian rheumatology context, we searched for appropriate interventions. The VTP had showed beneficial effects on psychological distress and pain in persons with chronic musculoskeletal pain. Persons with inflammatory

rheumatic diseases frequently report these symptoms as well. Additionally, the VTP explicitly addresses emotional responses to chronic conditions and the relations between thoughts, feelings and bodily symptoms in a way we did not find in existing interventions. Moreover, the VTP had integrated the recognition of patient perspectives of their condition and taken seriously that persons with chronic conditions have their own knowledge and ability to create meanings in their situations. Finally, the training of awareness (mindfulness) in combination with creative methods and focus on resources and possibilities rather than strategies to reduce symptoms, is an innovative approach that has previously not been investigated in persons with chronic rheumatic diseases.

3. Aims of the study

The main aims of this research project were 1) to evaluate the clinical effects of the VTP in patients with chronic rheumatic diseases, 2) to explore participant experiences of the VTP, and 3) to test the measurement properties of the Emotional Approach Coping Scale (EAC), in Norwegian patients with rheumatic diseases.

The specific research questions were:

- Can VTP participation improve psychological wellbeing, self-efficacy and disease-related symptoms in persons with inflammatory rheumatic diseases and fibromyalgia? (paper I)
- Which factors predict reduction in psychological distress? (paper I)
- How do persons with rheumatic diseases experience VTP participation in terms of influence on their emotional wellbeing and coping behaviour? (paper II)
- By which processes do these influences arise? (paper II)
- Is EAC a valid instrument in Norwegian persons with rheumatic diseases? (paper III)
- Is EAC responsive to change in Norwegian persons with rheumatic diseases? (paper III)
- What are the effects of the VTP on psychological wellbeing, self-efficacy and emotion-focused coping, compared to routine care plus a CD with mindfulness-based home exercises, in persons with inflammatory rheumatic joint diseases? (paper IV)

4. Materials and methods

4.1 Methodological considerations

There is increasing understanding that both qualitative and quantitative methods are useful when studying complex interventions (151;152). The two methods generate different kind of knowledge that in combination contribute to a broader and more profound understanding of the mechanisms of the interventions (153). For this reason we used both quantitative and qualitative methods in the present research project. The quantitative methods allowed quantification of effects by studying associations between the variables, predictions and by comparing groups. The qualitative methods allowed more extensive descriptions of *how* the intervention worked according to participant experiences. We assumed that the data we obtained by using different methods would complement each other.

4.2 Study designs

Paper I was a longitudinal pre – post-test study with a one-year follow-up. Paper II was as a qualitative focus group study. The study of measurement properties of the EAC, reported in paper III, included both a cross-sectional design (validity) and a pre – post-test design (responsiveness). Paper IV was an RCT, in which participants were allocated to either VTP or a routine care control group that received a CD with mindfulness-based home exercises for individual voluntary use.

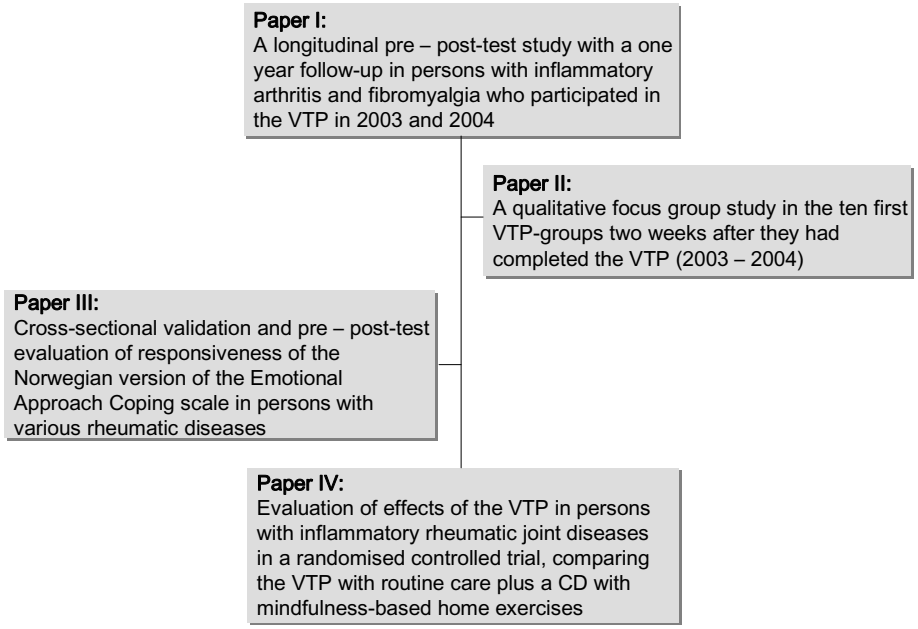

Figure 1: Overview of the project

4.3 The intervention

The VTP comprised ten group sessions over a 15 weeks period plus a booster session after approximately six months. Each session lasted for 4.5 hours and addressed a specific topic related to living with chronic illness (Table 2). The number of participants in each VTP group ranged from eight to twelve. Through various awareness exercises participants were encouraged to become aware of, and intentionally attend to, their emotions, thoughts and bodily senses without attempting to change or avoid them (mindfulness). In addition, creative exercises, such as guided imagery, music, drawing, poetry and metaphors were used to encourage active participation and provide opportunities for experiences and discoveries (see section 2.3.1.2). Reflections on own experiences were promoted through writing, sharing and listening to one another within the group. Between sessions participants performed awareness and relaxation training by listening to a CD with mindfulness-based

exercises, and they wrote reflective diaries (8). The group facilitators were responsible for allowing participants to choose if, and to what extent they would take part and engage in the different exercises and how much they wanted to share with others.

Table 2: Topics addressed in each group session

Session 1	Getting to know each other, presentation of group values "If my body could talk ….."
Session 2	"Who am I?" My personal resources
Session 3	"Who am I in relation to others?"
Session 4	Values: "What is important for me now?"
Session 5	What do I need? Knowing one's strengths and limitations
Session 6	Anger
Session 7	Joy
Session 8	Sorrow
Session 9	Individual resources, possibilities and choices
Session 10	Anchoring of discoveries and the way ahead

The following is an example from group session 6: Anger

The first part of the programme is common in all sessions: Participants are invited to share their reflections on experiences from home exercises after the previous session in groups of three to four persons. They are encouraged to read their reflective diaries for each other and to share and listen with an open, non-judgmental attitude without discussing or giving advice. Next, participants are invited to take part in an awareness exercise instructed by one of the group facilitators. They are guided to attend to their thoughts, feelings and bodily senses in the present moment with openness, acceptance and curiosity. After the exercise, they are invited to share their experiences with one other person in the group.

In the next part of the session, the group facilitators introduce the topic 'anger' by giving a short introduction about the relationship between chronic illness and emotions and the purpose of addressing emotions. The participants are then invited to take part in an exercise with awareness of anger, instructed by one of the facilitators: "Think of the word anger... or to be angry. Notice what you become aware of... thoughts, maybe concrete situations, perhaps memories from the past... Are the situations that you become aware of new or old? Maybe both?.... What do you

experience in your body right now when you think of anger or being angry?... Also note whether the word anger or being angry evokes any other feelings...”
Awareness of anger is continued in movement to music. The music allows participants to express anger with their body and they are invited to let their bodies do what they want to do while listening to the music. Then, written hypothetical sentences are used to enhance discovery of tacit knowledge, for example: “If there are any other emotions related to my feeling of anger, it must be...” Participants are further invited to share and reflect upon experiences and discoveries from the exercises in small groups and in a plenary session.
The next exercise is a guided imagery intending to help individuals to connect to their experiences of anger in the present moment, and to explore its meaning. Further, crayons and white papers are used to draw an image of anger as experienced here and now. Again, participants are invited to share and reflect in small groups and in plenary, with a focus on new discoveries and the consequences of these discoveries for the participants' daily life. Finally, they write a diary about their experiences from the whole session.
Before closing the session, participants are asked to be aware of how they relate both to their own anger and anger from others in their daily lives, and to listen to one track on the CD every day. They are also asked to write reflective diaries about their thoughts, emotions and bodily senses. The session ends with a relaxation exercise. Each session follows the same structure with exercises adapted to the particular topic.

4.4 Study participants

The study included participants from three different samples: 1] Patients who participated in the VTP in 2003 and 2004 (papers I and II). 2] Patients recruited for the purpose of testing the measurement properties of the EAC (paper III). 3] Patients included in the RCT 2007 - 2009 (paper IV).

4.4.1 The pre – post-test and focus group studies (papers I and II)

Persons with various rheumatic diseases were recruited from six rheumatology departments in southern Norway. Inclusion criteria were confirmed rheumatologic diagnosis, age 20 years or older and good understanding of Norwegian language. Health professionals at the rheumatology outpatient clinics and the rheumatology in-patient wards at the hospitals informed patients about the VTP courses, gave them information leaflets and invited them to attend open information meetings. Those who were interested after the information meetings enrolled in the VTP. If they also met the inclusion criteria they were asked to participate in the study.

A total of 213 patients took part in the open information meetings, 181 enrolled in the VTP and 175 agreed to study participation (Figure 2). Included patients had the following diagnoses: RA (n = 63), FMS (n = 63), PsA (n = 12), AS (n = 8), OA (n = 8), systemic lupus erythematosus (SLE) (n = 8), JIA (n = 2), Still's disease (n = 1), polyarthritis (n = 1) and other rheumatologic diagnosis (n = 9). One of the departments invited only patients with FMS to participate, because they considered the VTP to be a relevant treatment option for this group of patients to whom they had no other good treatments.

Three patients dropped out after only one session and were excluded from the study, resulting in 172 patients who completed the VTP. Twenty VTP groups were conducted between January 2003 and November 2004. Participants in the first 10 courses (n = 91), representing five of the rheumatology departments, were asked to take part in focus group interviews two weeks after they had completed the VTP, and a total of 69 patients agreed to participate in the interviews (Figure 2).

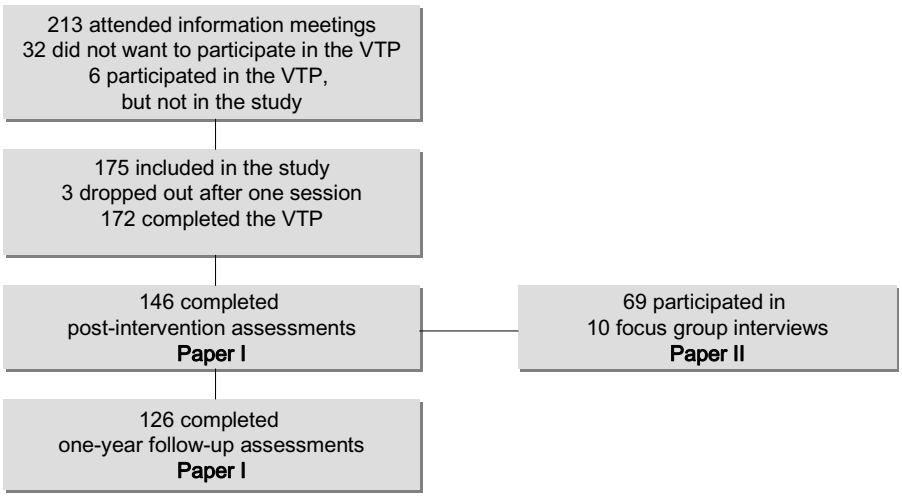

Figure 2: Flow chart of participants included in papers I and II

4.4.2 The study of measurement properties of the Emotional Approach Coping Scale (paper III)

Three patient groups were recruited in 2007. For the cross-sectional validation study 118 consecutive patients (group 1) who attended regular consultations at rheumatology inpatient wards, outpatient or day clinics at four different rheumatology departments were recruited. In addition, 49 patients (group 2) attending four VTP courses and 103 patients (group 3) attending five diagnosis-specific SMP courses were recruited for the pre – post-test study of responsiveness. All data from group 1 and baseline data from group 2 and 3 were used in the cross-sectional study (Figure 3).

Inclusion criteria were adults with confirmed rheumatologic diagnosis in the consecutive sample (group 1) and confirmed rheumatologic diagnosis of at least six months duration and age over 20 years in the two VTP- and SMP courses (group 2 and 3).

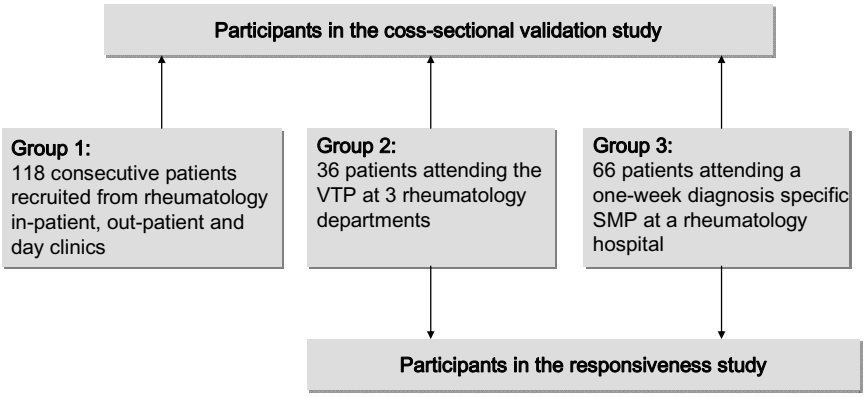

Figure 3: Participants included in paper III

4.4.3 The randomised controlled trial (paper IV)

Participants were recruited from three rheumatology departments in south-eastern Norway between March 2007 and June 2009. Inclusion criteria were inflammatory rheumatic joint disease diagnosed at least one year earlier and age between 20 and 70 years. Non-inflammatory diagnosis and inability to understand Norwegian language were exclusion criteria.

A project assistant at each department asked patients who regularly visited their clinics to participate. In addition, participants were recruited from random samples drawn from two registers at Diakonhjemmet Hospital in Oslo of patients fulfilling the ACR 1987 criteria for RA (154) and the New York classification criteria for AS (15). All interested participants attended information meetings chaired by the project assistants.

From a total of 814 invited persons, 113 attended the information meetings. Seventy-three persons were willing to participate in the study and were randomised: 37 to

VTP and 36 to the control group. Sixty-eight persons completed the assessments post-treatment (34 in each group), and 67 completed the 12-month assessments (34 in VTP and 33 in control).

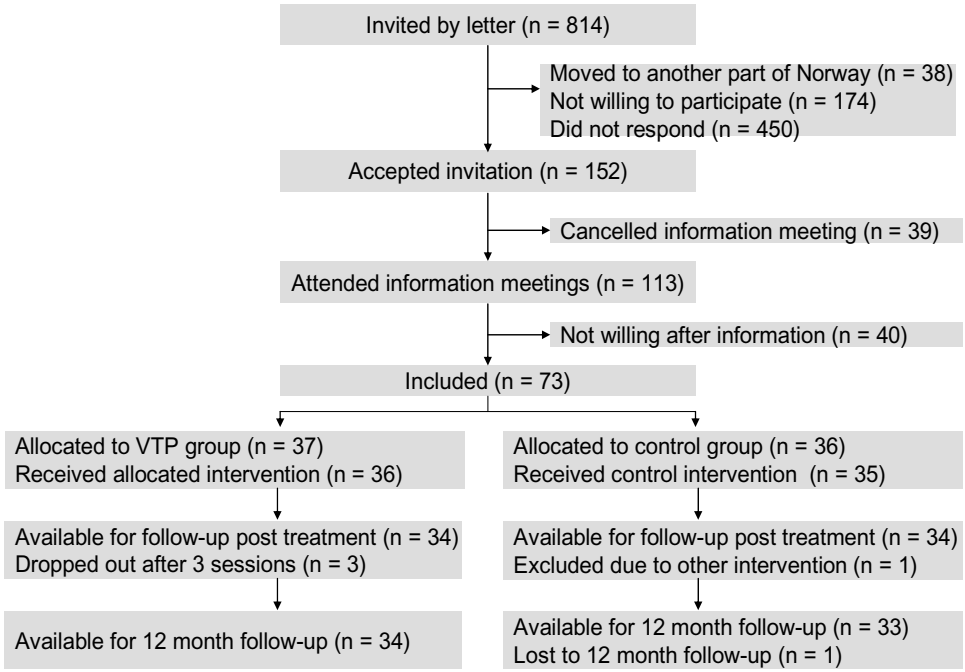

Figure 4: Flow chart of participants in paper IV

4.5 Data collection

4.5.1 Quantitative evaluation of the VTP (papers I and IV)

In the pre – post - VTP evaluation data were collected through comprehensive self-report questionnaires before the intervention (baseline), immediately after the intervention and 12 months after completion of the intervention. Questionnaires were given to the participants by the group facilitators before the first and after the last

VTP-session. The one-year follow-up questionnaires were sent to participants with a postage-paid return envelope.

Participants in the RCT were assessed by a comprehensive self-report questionnaire at baseline, post-intervention and 12 months from baseline. The 12-month follow-up was accelerated compared to the pre – post-test study, so that the control group should not have to wait too long for possible VTP participation. All questionnaires were sent to participants with a postage-paid return envelope.

There is a considerable day-to-day variation in self-reported symptoms in patients with inflammatory rheumatic joint diseases (155). Thus, in order to reduce between-person variation, selected outcomes (pain, fatigue, wellbeing, self-care ability and self-reported disease activity, see section 4.6 and Table 4) were measured by telephone interviews four times at two-week intervals at baseline, post-intervention and at 12-month follow-up in addition to being included in the questionnaires. This gives a total of five measurements at each assessment point. By the repeated measurements, we assumed to get a more reliable value of these measures. The participants had the questionnaires in front of them during the telephone interviews.

4.5.2 Qualitative evaluation of the VTP (paper II)

Qualitative data were obtained from focus group interviews approximately two weeks after the VTP. Three different experienced interviewers, all with good knowledge of the VTP, but who had not facilitated any of the groups, moderated the interviews. A semi-structured interview guide was used as a checklist (Table 3). The interviewers aimed at being responsive to any issues as they arose within the group and creating an open conversation, in which all participant views could be comprehensively explored, particularly divergent experiences and critical issues. The interviews lasted 1 - 1.5 hours, were audio taped and transcribed verbatim. No names were used in the interviews, and all data were de-identified to ensure confidentiality. The group facilitators did not take part in the interviews.

Table 3: Semi-structured interview guide

How did you experience to be part of the VTP?
Have any of the topics been especially important to you?
Do you think any topics should have been excluded?
Have you had any negative experiences from participating in the VTP?
Has participation in the VTP in any way been of importance to your daily life?
How did you experience relating to the different topics in a group context?
How was your relationship to the other group participants?
Has it in any way been important for you to listen to the CD with different exercises?
How did you experience the various methods used in the VTP?
Have the group facilitators in any way been important to you?
What do you thing about the way the group was organised?
Is there anything else you want to say?

4.5.3 Evaluation of measurement properties of the Emotional Approach Coping Scale (paper III)

For the cross-sectional study self-report questionnaires were given to patients at a single data collection point. The patients who were consecutively included from the rheumatology departments (group 1), got the questionnaires from a rheumatology nurse and were given the choice of filling it out in the waiting-time at the clinic or bringing it home and return it in a postage-paid return envelope. Participants in the VTP (group 2) got the questionnaires from the group facilitators immediately before the first VTP-session, and questionnaires were sent with a postage-paid return envelope after the last session. Participants in the one-week SMP (group 3) were given the questionnaires by a nurse at the beginning of the first day and at the end of the last day of the course. All questionnaires were marked with an id-number and returned anonymously to the project leader for plotting and analyses.

4.6 Measures in the studies

All measures were self-reported, except for age, diagnoses, and disease duration, which were obtained from the patients' records. The measures are listed in Table 4.

4.6.1 Demographic and disease variables

Age, gender, marital status, work status, rheumatologic diagnosis, disease duration (i.e. time since diagnosis) and duration of symptoms were included in all papers. Additionally, education, use of medication and co-morbidity were included in paper IV.

4.6.2 Physical function

Physical function was measured by the Stanford Health Assessment Questionnaire (HAQ) (156) in paper I and by the Stanford Modified Health Assessment Questionnaire (MHAQ) (157;158) in paper IV. HAQ covers eight activity performance categories, such as dressing, rising, eating, walking, hygiene, reaching, gripping and daily activities. In MHAQ these items are collapsed to eight activities of daily living. Both instruments are scored on a scale ranging from 0 (without difficulty) to 3 (unable to do). In paper IV self-reported physical activity was included as an ordinal variable with the answering categories “no activity”, “0.5 - 1 hour/week”, “1 - 2 hours/week”, “3 - 4 hours/week”, and “more than 5 hours/week” and then dichotomised into “less than 2 hours/week” and “more than 2 hours/week”.

Table 4: Overview of measures included in papers I – IV

Demographic and disease variables		**Included in paper**
Age (years)		I, II, III, IV
Gender (male/female)		I, II, III, IV
Marital status (living with/without partner)		I, II, III, IV
Education (less/more than 12 years)		IV
Employment (paid work: yes/no)		I, II, III, IV
Diagnosis		I, II, III, IV
Disease duration (years since diagnosis)		I, II, III, IV
Symptoms duration (years)		I, II, IV
Medication (type)		IV
Co-morbidity (yes/no)		IV
Physical function	**Item scoring**	**Included in paper**
Health Assessment Questionnaire (HAQ)	0 – 3, 0 = without difficulty	I
Modified Health Assessment Questionnaire (MHAQ)	0 – 3, 0 = without difficulty	IV
Physical Activity	</= 2 hours/week / > 2 hours/week	IV
Psychological wellbeing		
General Health Questionnaire-20 (GHQ-20)	0 – 3, 0 = no distress	I, III, IV
Wellbeing (VAS/NRS)	0-100, 0 = very well/ 0-10, 10 = very well	I / IV
Coping		
Arthritis Self-Efficacy pain Scale (ASES pain)	10 – 100, 100 = totally confident	I, IV
Arthritis Self-Efficacy symptoms Scale (ASES symptoms)	10 – 100, 100 = totally confident	I, IV
Emotional Approach Coping Scale (EAC)	1 – 4, 4 = high processing/ expression of emotions	I, III, IV
Self-care ability (VAS/NRS)	0-100, 0 = very good/ 0-10, 10 = very good	I / IV
Brief Approach/Avoidance Coping Questionnaire (BACQ)	1 – 4, 4 = high approach-oriented coping	III
Disease-related symptoms		
Pain (VAS/NRS)	0-100/0-10, 0 = no pain	I / IV
Fatigue (VAS/NRS)	0-100/0-10, 0 = no fatigue	I / IV
Patient Global disease Activity (PGA), (VAS/NRS)	0-100/0-10, 0 = no activity	I /IV

VAS = Visual Analogue Scale, NRS = Numerical Rating Scale

4.6.3 Psychological health and wellbeing

4.6.3.1 Psychological distress

Psychological distress was assessed by the General Health Questionnaire, 20-item version (GHQ-20) (159;160). The GHQ-20 measures several aspects of psychological health during the previous two weeks and is balanced between positively phrased items, indicating psychological health, and negatively phrased items, indicating psychological distress. In studies measuring change, scoring on a four point Likert scale (0 to 3) is recommended (159;161). This gives a possible sum score of between 0 (no distress at all) and 60 (much more distress than usual). The GHQ is a widely used screening instrument for psychological distress and is also found to be sensitive to changes in distress over time (160;162). A suggested threshold for serious psychological distress is a sum score above 23 (161;163). The GHQ-20 has been validated and used in various samples of chronically ill persons in Norway (161;163;164). The GHQ-20 was the primary outcome measure in paper I and IV, and was used for measuring construct validity in paper III.

4.6.3.2 Overall wellbeing

In paper I, patient perceptions of overall wellbeing was assessed by a 100 mm Visual Analogue Scale (VAS) with the question "How *are* you now?" The scale was anchored by 0 (very well) and 100 (very bad). In paper IV, the same question was assessed by a Numerical Rating Scale (NRS) and reversed, thus scored from 0 (very bad) to 10 (very good). The reason for the change of scales from VAS to NRS was that the measures were used in telephone interviews, in which it was necessary to answer by an exact number.

4.6.4 Coping measures

4.6.4.1 Self-efficacy

Self-efficacy is the confidence that one is capable of achieving a specific behaviour or a cognitive state (84;88;165) and is assumed to facilitate behaviour change that can alter health outcomes (86;109). Self-efficacy was assessed in paper I and IV by two subscales of the Arthritis Self-Efficacy Scale (85), self-efficacy pain (5 items) and self-efficacy symptoms (6 items). Each item is scored from 10 (not at all confident) to 100 (totally confident). For each subscale scores are summed across the items and divided by the number of items. A Norwegian translation has been used in previous prospective studies in RA patients (90;166).

4.6.4.2 Emotion-focused coping

Emotion-focused coping was assessed by the Emotional Approach Coping scale (EAC) that measures ability to acknowledge, understand, and express emotions (101). The EAC comprises 16 items that form two subscales: emotional processing (eight items), for example "I realise that my feelings are valid and important" and emotional expression (eight items), for example "I allow myself to express my emotions". Each item is scored from 1 (not at all) to 4 (in high degree). The mean item score is calculated for each subscale. The Norwegian translation of the EAC was validated in paper III.

4.6.4.3 Approach/avoidance coping

The Brief Approach/Avoidance Coping Questionnaire (BACQ) was used to measure construct validity of the EAC in paper III. The BACQ comprises 12 items designed to measure a general concept of approach-oriented versus avoidance-oriented coping. Items are scored on a 5-point Likert scale from "strongly disagree" to "strongly agree". Examples of approach-oriented items are: "I say so if I am angry or sad" and "I make an active effort to find a solution to my problems". Examples of avoidance-oriented items are: "I bury myself in work" and "I try to forget my problems". The

BACQ was found to have satisfactory measurement properties in a Norwegian population of primary care patients (75).

4.6.4.4 Self-care ability

Patients' perception of self-care ability was assessed by 100 mm VAS with the question "How will you describe your ability to take care of yourself in everyday life?" The scale was anchored by 0 (very good) and 100 (very bad) (10). In paper IV, the same question was assessed by NRS and reversed, thus scored from 0 (very bad) to 10 (very good).

4.6.5 Symptoms and disease activity

In paper I, patients' perceptions of pain and fatigue were measured by 100 mm VAS anchored by 0 (no pain/fatigue) and 100 (intolerable pain/fatigue). Patient global disease activity (PGA) was assessed by the patient global 100 mm VAS anchored by 0 (good/no symptoms) and 100 (very bad symptoms). In paper IV, the same assessments were performed by NRS, scored from 0 (no pain/fatigue/symptoms) to 10 (intolerable pain/fatigue/very bad symptoms).

4.7 Sample size, randomisation and blinding in the randomised controlled trial

4.7.1 Sample size calculation

The GHQ-20 was selected as a primary outcome measure and used for sample size calculation in the RCT. There are no clear recommendations in the literature about what a clinically relevant change in the GHQ-20 might be. In the pre – post-test study we found a 10% reduction in GHQ-20 in patients with IA at one-year follow-up (mean change 6.0, see Main results section 5.1). With a power of 80%, a significance level of 0.05 and anticipating that we would find a mean change difference of 5.0 between the groups in the RCT, we calculated the sample size as 72 participants in

each group. To manage the study within a reasonable time frame we would have to reduce the sample size, but still keep the power. A previous study in Norwegian RA patients has shown that using up to five repeated measurements per patient can decrease the between-person standard deviation (SD) and consequently the number of patients required in a trial by as much as 20% (167). We therefore conducted a small pilot study in which we calculated the individual means for five repeated measurements on GHQ-20 at baseline and the follow-up visits. Based on this study we hypothesised that the RCT would detect a difference between groups of 4.5 in GHQ-20 with an estimated SD of 3.9, and a probability of a slight improvement of 0.9 in the control group. A bootstrap procedure was performed, and the sample size was calculated to 34 in each group.

4.7.2 Randomisation and blinding

A statistician generated randomisation lists, using Statistical Analysis Software (SAS) version 9.1.3. The randomisation lists were based on blocks of 10 and 15 for each department to ensure approximately equal sample sizes. Participants from each department were given consecutive numbers and a person not involved in the data collection or intervention, allocated each participant to the corresponding number on the randomisation list.

The persons who conducted the telephone interviews were blinded for group assignments, and participants were instructed not to discuss their intervention with the interviewer. A blinded statistician conducted the primary statistical analyses, and the randomisation code was not opened until these analyses were completed.

4.8 Analyses

Qualitative analyses were carried out manually. For statistical analyses the Statistical Package for Social Science, version 14 (IBM SPSS Statistics©) and the Statistical

Analysis Software, version 9.2 (SAS Institute Inc©) were used. The level of statistical significance was set at $\alpha = 0.05$ for all analyses.

4.8.1 Statistical methods and analyses of quantitative data

Descriptive statistics for baseline values in papers I, III and IV were calculated as means and standard deviations (SD) for continuous variables and as percentages for categorical variables. If a variable had a skewed distribution, median was calculated instead of mean.

4.8.1.1 Analyses in paper I

Baseline differences between completers and non-completers of the one-year follow-up assessments were examined by two-sample independent t-test for continuous variables and Pearson's chi-squares for categorical variables.

Paired t-tests were used to examine changes in outcome variables from baseline to post-intervention and from baseline to one-year follow-up. First, analyses of changes were calculated for all participants. Second, the sample was divided into three diagnostic groups: the IA-group (i.e. RA, AS, PsA, JIA, Still's disease and polyarthritis), the FMS-group and the group of "others" (i.e. OA, SLE, others). The latter group was excluded from the further analyses because of its heterogeneity and small number. Effect sizes (ES) for the change scores were calculated as standardised response means (SRM) by dividing mean change for each outcome measure by the SD of the change score (168;169). The values of the SRMs were interpreted according to Cohen's effect size index, in which less than 0.20 is considered trivial, 0.20 – 0.49 is considered a small difference, 0.50 – 0.79 a moderate difference and more than 0.80 a large difference (169;170).

Possible predictors of change in psychological distress from baseline to one-year follow-up were explored by bivariate and multivariate regression analyses. Age, disease duration, diagnosis (IA and FMS) and the baseline values of ASES pain and symptoms, wellbeing, self-care ability, pain, fatigue, PGA and HAQ were chosen as

predictor variables and entered into a bivariate regression model with change in GHQ-20 from baseline to one-year follow-up as the dependent variable. The procedure used for the multivariate regression model was Hosmer's manually backward elimination technique (171). All variables that were significant at the 0.30 level in the bivariate analyses were included in the initial multivariate model. At each step, the least significant variable was removed. This process continued until only significant variables remained in the model. All included variables were tested for confounding. In the final model interactions and model assumptions were assessed using Cook's distance (Cook's d) and Jackknife residuals. Interactions were included only if they were significant at the 0.05 level.

4.8.1.2 Analyses in paper III

The purpose of the analyses in this paper was to test the Norwegian version of the EAC for data quality, internal consistency reliability, construct validity and responsiveness to change.

In order to assess the acceptability of the instrument, levels of missing data were assessed for all items. Evidence for the existence of the two EAC subscales was assessed by principal component analyses (PCA) with varimax rotation (172). Components with eigenvalues greater than one were considered potentially important. Internal consistency was assessed by item-total correlations and Cronbach's alpha. For a scale to be sufficiently reliable for use in groups of patients, an alpha value of between 0.70 and 0.90 was considered acceptable (173;174). Because no 'gold standard' for assessing emotional approach coping exists, criterion validity was not assessed.

A construct can be thought of as a "mini-theory" to explain the relationships among various behaviours and attitudes. Construct validation is an ongoing process of learning more about the construct, making new predictions, and then testing them (174). To assess the construct validity of the EAC, we compared the scale with two other instruments, the BACQ, which measures approach and avoidance-oriented

coping, and the GHQ-20, which measures psychological distress. Pearson's correlation coefficient was used to calculate the correlations between the instruments (174;175). Because the EAC-scales were designed to measure approach-oriented coping, we hypothesised that the EAC scores would be positively correlated with the approach-oriented items in the BACQ. However, the EAC-scales and the BACQ measure different aspects of coping, and hence correlations with the BACQ were expected to be low to moderate (0.3 - 0.6). Furthermore, because the EAC-scales were intended not to be interfered with distress-related content (101), we expected low level (< 0.3) negative correlations with GHQ-20.

Responsiveness refers to an instrument's ability to measure change over time (174;176;177). This was assessed in the VTP and the SMP samples by paired samples t-tests and the magnitude of the changes were compared by the SRMs. Because processing and expression of emotions are more explicitly addressed in the VTP than in the SMP, and the VTP is of longer duration (15 versus one week), we hypothesised that participants in the VTP would have a larger increase in the EAC scores compared to participants in the SMP.

4.8.1.3 Analyses in paper IV

All outcome variables in this paper were continuous and results were reported as mean values with confidence intervals (CI).

The average mean values of the five repeated measurements, as well as the single means of variables measured once at each time point, were used in the analyses. Treatment effects (mean differences between the groups post-treatment and at 12 months) were estimated with mixed models repeated measures analysis. This model includes the interaction of treatment and time (i.e. post-treatment and 12 months). We adjusted for age, gender, disease duration, education, and marital status, as well as for the individual baseline values for each outcome, but none of these were significant in any model, and they were therefore removed in the final model. The mixed models analysis is robust to missing values because the patients are included at time points

with non-missing values only. A parametric bootstrap procedure was applied to ascertain the robustness of the findings. The model assumptions were assessed using Cook's d and Covratio statistics for individuals as well as for the estimated covariance. The treatment effect sizes (Cohen's d) were calculated as the adjusted between-group difference in scores at 12 month follow-up divided by the pooled SD of the baseline scores for each variable (178).

4.8.2 Analyses of qualitative data

A secretary transcribed all the audio taped focus group interviews verbatim. The data were analysed by an inductive content analyses approach. This approach implies moving from the specific to the general, so that particular instances are observed and then combined into a larger whole or general statement (179;180). Two researchers independently read transcripts from each focus group interview several times and notes and headings were written in the texts (i.e. open coding). Codes were then categorised according to the topics in the interview guide. The two researchers compared their analytical codes and categories, differences were negotiated and new categories were formed. Transcripts were read again and any themes that were not covered by the interview guide were identified. Descriptions of feelings and emotional processes were especially looked for, as well as disagreements within groups. A third experienced qualitative investigator read abstracts from the transcripts, and analyses were discussed with her to ensure that all themes were comprehensive and inclusive. Coded themes were compared across the groups in order to identify similarities and differences, and then grouped into broader categories, using content-characteristic words (180). The categories and selected citations from the texts were discussed with a group of co-researchers. Finally, the identified categories were grouped according to the aims of the study, as covering either types of influences that arouse from the intervention or the processes whereby influences arouse. A professional translator translated the quotes that were chosen to illustrate the analytic categories into English.

4.9 Ethical aspects

All studies were conducted according to the principles of the Declaration of Helsinki. Because the VTP is an intervention, in which the participants are invited to take active part in the different exercises and to share their thoughts and emotions, it was particularly important to provide thorough information in advance. The study was explained in a letter, in which the patients who were interested, were invited to an information meeting. In this meeting they got extensive information about the intervention and the study before they decided to take part. All participants gave their written consent. The Regional Committee for Medical Research Ethics and the Data Protection Supervisor ("Personvernombudet ") at Oslo University Hospital (previously Ullevål University Hospital) approved the studies.

The education program for group facilitators ensured that they were qualified to deliver the VTP with appropriate knowledge and skills and to manage the group processes and individual reactions that might occur. They were obligated to maintain secrecy about all information from the group participants.

5. Main results

5.1 Improvements in persons with inflammatory rheumatic diseases and fibromyalgia after participation in the VTP (paper I)

146 (83%) patients answered the questionnaires post intervention and 126 (72%) at one-year follow-up. No significant differences were found in baseline scores between those who completed questionnaires at one-year follow-up and those who did not. When the diagnoses grouped as "others" were excluded, 128 remained post intervention (IA = 76, FMS = 52) and 114 (IA = 70, FMS = 44) at one-year follow-up. Psychological distress, wellbeing, self-efficacy pain and symptoms and self-care ability were significantly improved in the IA group after intervention, and the improvements were maintained at one-year follow-up (all p-values < 0.001, SRMs ranged from 0.63 to 0.41) (Table 5). No significant reduction was found in fatigue after intervention, but at one-year follow-up fatigue was significantly reduced in the IA group ($p = 0.007$). There was also a small reduction in pain at one-year follow-up ($p = 0.03$). No statistically significant improvements were found in any variables in the FMS group (Table 5).

The bivariate regression analyses showed that wellbeing, diagnosis and fatigue were the main predictors of change in psychological distress. In multivariate regression analyses IA diagnosis and higher scores of fatigue at baseline were the main predictors of reduction in psychological distress at one-year follow-up, after adjusting for all other variables (Table 6).

From these findings we hypothesised that the VTP can reduce psychological distress and improve self-efficacy and wellbeing in patients with IA. There was no support for such improvements in patients with FMS. We concluded that a controlled trial was needed to further test and possibly confirm these results.

Table 5: Baseline scores and mean change from baseline to post-intervention and from baseline to 12-month follow-up for patients with inflammatory arthritis (IA) and fibromyalgia syndrome (FMS)

	Baseline (N=150) Mean (SD)	**Post-intervention** (N=128) Mean (95% CI)	P-value*	**12 months** (N=114) Mean (95% CI)	P -value*	**SRM** (12 months)
Psychological distress (GHQ-20) (0 - 60, 0 = no distress)						
IA	23.1 (9.5)	-8.2 (5.9 to 10.5)	< 0.001	- 6.0 (3.3 to 8.7)	< 0.001	0.52
FMS	27.4 (11.0)	- 4.2 (- 0.2 to 8.6)	0.06	- 0.02 (- 4.5 to 4.5)	0.99	0.00
Wellbeing (VAS 0 - 10, 0 = very good)						
IA	42.1 (24.2)	-12.0 (6.8 to 17.2)	< 0.001	-13.7 (8.5 to 19.0)	< 0.001	0.63
FMS	51.6 (21.7)	- 6.6 (- 0.7 to 13.8)	0.07	- 5.5 (- 3.0 to 14.0)	0.20	0.02
Self-efficacy pain (10 - 100, 100 = high)						
IA	54.2 (18.7)	6.6 (- 9.6 to -3.6)	< 0.001	9.0 (- 13.4 to -4.5)	< 0.001	0.48
FMS	48.3 (16.3)	- 1.0 (- 3.7 to 5.7)	0.68	- 1.5 (- 7.2 to 4.1)	0.59	0.08
Self-efficacy symptoms (10 - 100, 100 = high)						
IA	62.8 (13.6)	6.2 (- 9.1 to - 3.2)	< 0.001	6.7 (- 9.8 to -3.6)	< 0.001	0.53
FMS	55.5 (15.4)	- 0.2 (- 4.7 to 5.1)	0.95	3.3 (- 8.4 to 1.9)	0.21	0.19
Self-care ability (VAS 0 - 10, 0 = very good)						
IA	32.5 (23.3)	- 6.9 (1.7 to 12.0)	0.01	- 8.5 (3.6 to 13.5)	< 0.001	0.41
FMS	37.2 (27,4)	2.9 (- 9.0 to 3.3)	0.36	3.9 (-12.9 to 5.1)	0.39	0.13
Pain (VAS 0 - 10, 0 = very good)						
IA	45.7 (24.1)	- 7.1 (1.3 to 12.8)	0.02	- 6.7 (0.8 to 12.7)	0.03	0.27
FMS	60.1 (18.8)	- 1.9 (- 4.4 to 8.1)	0.55	- 2.0 (- 6.0 to 9.9)	0.62	0.01
Fatigue (VAS 0 - 10, 0 = very good)						
IA	57.0 (28.0)	- 4.8 (- 1.0 to 10.6)	0.10	- 8.7 (2.4 to 14.9)	0.007	0.33
FMS	74.6 (20.5)	- 2.7 (- 4.3 to 9.6)	0.44	- 7.0 (- 1.1 to 15.2)	0.09	0.27
PGA (VAS 0 - 10, 0 = very good)						
IA	46.9 (22.9)	- 5.3 (- 0.2 to 10.8)	0.06	- 3.8 (- 1.4 to 8.9)	0.15	0.18
FMS	60.1 (19,4)	- 0.2 (- 6.4 to 6.7)	0.96	- 0.3 (- 6.1 to 6.6)	0.93	0.01

*Paired sample t-tests, SRM = Standardised response mean (< 0.2 = trivial, 0.2 – 0.49 = small, 0.5 – 0.79 = moderate, ≥ 80 = large), IA = Inflammatory Arthritis, FMS = Fibromyalgia syndrome, VAS = Visual Analogue Scale, PGA = Patient Global Disease Activity,

Table 6: Predictors of change in psychological distress at one-year follow-up

	Bivariate analysis*			Multivariate analysis*		
Predictor variables	Coefficient	95% CI	P-value	Coefficient	95% CI	P-value
Wellbeing (VAS)	0.12	(0.03 to 0.21)	0.01			
Fatigue (VAS)	0.09	(0.02 to 0.17)	0.03	0.17	(0.08 to 0.26)	<0.001
Diagnosis:			0.02			
IA	5.98	(1.07 to 10.89)		9.74	(4.69 to 14.79)	<0.001
FMS	reference			reference		

* Linear regression analysis, IA = inflammatory arthritis, FMS = fibromyalgia syndrome, VAS = Visual Analogue Scale (0 - 100, 0 = no pain/fatigue/high wellbeing)

5.2 Persons with rheumatic diseases' experiences from participation in the VTP (paper II)

A total of 69 patients took part in the focus groups. Five main categories were identified from the data analyses: 1) recognizing oneself as both ill and healthy, 2) recognizing own emotions, 3) awareness of own needs, 4) being part of a community and 5) being recognized as a credible patient. The first three categories were related to the type of influence participants experienced from the intervention, and the last two categories were related to the processes by which influences arouse. Quotes that illustrate each category are shown in Table 7.

Table 7: Categories and illustrating quotes identified in the focus group interviews

Category	Quotes
1. Recognizing oneself as both ill and healthy	"For me personally, it is important not just to be an ill person. I mean the fact that I am a whole person even though I have a chronic disease. Yes, they [the topics in the VTP] reminded me of it. I got it confirmed that I really am a whole person in spite of being an ill person. I realize this, but it really makes a difference to work on it. I am not only a disease, I am so much more" (IA-group 5). "I have never liked my weak side, like needing rest and care and such, I have never really liked this. Now I just have to accept it. And in fact I really like this side of myself, it is more human, I think it has completely different facets" (FMS-group 2).
2. Recognizing own emotions	"It has been very important to acknowledge my sorrow over no longer being healthy. It is a fundamental feeling, as we are of course in the middle of life and everyone else is healthy and they expect that we are too, and there we are feeling desperate at having lost something that is so valuable" (FMS-group 2). "I feel such a lack of energy that I haven't been able to work. This has been a great sorrow for me personally… As I am so young, this should not break me down, so I have done my best, cried, and hoped that no-one would notice that I wasn't well... In fact my problem was that it was difficult to accept my situation. I kinda felt that I was not worth so much anymore, couldn't cope with my job any more" (FMS-group 1). "I have started to understand that anger can be very positive and that I need it in any case, because then you get rid of tension, and in a way you may get rid of a big heavy backpack, like we were talking about, and as I said, now I only have a small nylon knapsack. Anger has kinda developed into something that lets you set limits, and you are even allowed to say no" (IA-group 3).
3. Awareness of own needs	"Help! I had said 'no' to someone. I don't usually do this. So it was very peculiar to think about after I had done it. ... I usually only say 'yes' …, but now I have been better at thinking of myself ... Those round me respect me when I say 'no' ... absolutely, they have always said that I should think more of myself. In fact, I really said 'no' before, but with a really bad conscience and stomach-ache, but now I say 'no' with a far better conscience" (IA-group 7).

Table 7: Continued	
Category	Quotes
4. Being part of a community	"What has been most important for me has been meeting other people with the same condition, or at any rate with a chronic condition that affects their daily life, and then being allowed to talk about all the negative feelings that I have had, all my defeats, my anger, disappointments and vulnerability, which have been difficult to cope with outside this group" (IA-group 2). "I'd never met anyone with this diagnosis before and I felt very much on my own. Now, I know several others, and I don't feel so alone any more" (FMS-group 1).
5. Being recognized as a credible patient	"When I got this [invitation] letter, I thought, is there really anyone who takes this seriously and believes me? This was an incredible experience for me" (FMS-group 1). "It is like a burden being lifted off me. A heavy backpack, to put it like that. I am not lazy, I am ill and I can do something about it, as now that I know what it is, I have completely different resources, masses of energy has been released" (FMS-group 2).

The VTP had enhanced participants' recognition of their disease-related emotions and helped them to relate more actively to their own needs. The study illuminated how the VTP, by combining topics related to life rather than the disease with awareness (mindfulness) and creative exercises and adaptive emotional expression, had enhanced emotional wellbeing and adaptive coping behaviour in patients with various rheumatic diseases.

5.3 Validity and responsiveness of the Emotional Approach Coping Scale in Norwegian persons with rheumatic diseases (paper III)

A total of 220 patients were included in the cross-sectional study; 118 in group 1, 36 in group 2 and 66 in group 3. Group 1 (patients attending the rheumatology clinics) had a significantly higher proportion of men ($p < 0.001$) and significantly longer disease duration than the two others ($p < 0.001$). Group 2 (patients attending the VTP) were significantly younger than the two other groups ($p = 0.03$). No significant differences were found for other variables assessed at baseline.

The EAC had low levels of missing data, ranging from 5.7% to 1.9%, for items relating to Emotional Processing and Emotional Expression, respectively. Mean item

scores (SD) ranged from 2.51 (0.89) to 3.32 (0.66). Results from principal component analysis supported the two subscales, Emotional Processing and Emotional Expression, which both had high Cronbach's alphas of 0.92 and 0.90, respectively (Table 8). These two components accounted for 62.7 % of the total variance.

Tabell 8: Component loading and Cronbach's alpha for the Emotional Approach Coping Subscales (Emotional processing and Emotional Expression)

Scale/item	Component loading*	Cronbach's alpha
Emotional Processing		0.90
I take the time to figure out what I'm really feeling	0.71	0.88
I delve into my feelings to get a thorough understanding of them	0.81	0.88
I realize that my feelings are valid and important	0.58	0.90
I acknowledge my emotions	0.46	0.90
I work on understanding my feelings	0.84	0.88
I explore my emotions	0.80	0.88
I find a way to understand my emotions better	0.80	0.88
I look closely at the reasons for my feelings	0.85	0.88
Emotional Expression		0.92
I take time to express my emotions	0.62	0.91
I let my feelings come out freely	0.79	0.91
I allow myself to express my emotions	0.85	0.90
I feel free to express my emotions	0.75	0.91
I express the feelings I am having	0.86	0.90
I find a way to express my emotions	0.62	0.92
I let my feelings out	0.87	0.90
I get my feelings out in the open	0.82	0.90

*Emotional processing and emotional expression had eigenvalues of 2.79 and 7.25 respectively

As hypothesised the EAC was positively correlated with approach-oriented items in the BACQ in the range 0.17- 0.50. There were no significant correlations between the EAC scales and the avoidance-oriented items in BACQ. The EAC Expression scale had a low and significant negative correlation with the GHQ-20 of - 0.13, i.e. higher emotional expression was associated with lower distress, which supported the hypothesis that the EAC items do not measure aspects of emotional distress.

Twenty-six (72%) of the included patients in the VTP and all included patients in the SMP completed the questionnaire after the intervention. As hypothesised the EAC scores increased more in the VTP group than in the SMP group. In the VTP group,

both EAC Processing and EAC Expression increased significantly, with SRMs 0.47 and 0.70, respectively. There were no significant changes in the EAC scales in the SMP sample at follow-up (Table 9).

Table 9: Responsiveness of the EAC in the VTP (n = 26) and the SMP (n = 66) calculated by paired samples t-tests

	Baseline mean (SD)	**Follow-up** mean (SD)	**Change scores** mean (SD)	**SRM**
EAC processing (1 - 4, 4 = high processing)				
VTP (15 weeks)	3.12 (0.60)	3.39 (0.64)	- 0.27 (0.58)*	0.47
SMP (1 week)	2.83 (0.66)	2.93 (0.66)	- 0.10 (0.52)	0.19
EAC expression (1 - 4, 4 = high expression)				
VTP (15 weeks)	2.69 (0.64)	3.06 (0.56)	- 0.37 (0.53)**	0.70
SMP (1 week)	2.76 (0.63)	2.82 (0.57)	- 0.06 (0.45)	0.13

VTP = Vitality Training Program (15 weeks), SMP = Self Management Program (one week)
* $P < 0.05$, ** $P < 0.001$. Values refer to statistical differences in mean scores between baseline and post-intervention, SD = standard deviation, SRM = standardised response mean

The EAC was found to be acceptable and valid for measuring emotional processing and expression in Norwegian patients with rheumatic diseases. The EAC scales were responsive to change in the VTP, which was considered to be an intervention that promoted emotional awareness.

5.4 Clinical effects of the VTP in persons with inflammatory rheumatic joint diseases (paper IV)

Seventy-three persons were randomised, 37 to the VTP and 36 to the control group. The VTP and control groups were well matched at baseline with regard to demographic and disease variables and all outcome measures; p-values ranged from 0.13 to 0.95. Ten persons in the control group and 13 in the VTP group exceeded the GHQ-20 threshold of 23.

Sixty-eight persons (93%) were available for follow-up post-treatment (34 in each group), and 67 (92%) completed the 12-month assessments (34 in VTP and 33 in control). Significant treatment effects in favour of the VTP were found post-treatment, and effects were maintained at 12 months in the primary outcome psychological distress and the co-primary outcomes self-efficacy pain and symptoms

and emotional processing. Treatment effects in psychological distress post-treatment and 12 months had effect sizes of 0.73 and 0.58, respectively. Other effect sizes ranged from 0.92 (self-efficacy symptoms) to 0.43 (emotional processing). No significant between-group differences were found in emotional expression (Table 10). In the VTP group, the number of persons exceeding the GHQ-20 threshold of 23 was reduced from 13 (36%) at baseline to 2 (6%) at 12 months, compared with from 10 (29%) to 8 (24%) in the control group ($p = 0.045$).

Significant treatment effects in favour of the VTP were also found post-treatment and at 12 months in the secondary outcomes fatigue, self-care ability and wellbeing. In the VTP group, improvement in fatigue was increased at 12 months, whereas the control group was unchanged from baseline. Effects in pain and the patient global assessment of disease activity did not reach statistical significance (Table 10).

The results show that the VTP can be considered a beneficial complement to existing treatment for patients with inflammatory rheumatic joint diseases, particularly for people who experience heightened psychological distress and fatigue.

Table 10: Mean (95% CI) scores and treatment effects (differences post-treatment and 12 months) and overall p-values estimated with mixed models linear repeated measures analysis*

	VTP Group	Control group	Effect (95% CI)	p-value
Primary outcome				
Psychological distress (GHQ-20) (0–60, 0 = no distress)**				0.002
Baseline	19.9 (17.8 to 22.1)	19.8 (17.5 to 22.0)		
Post-treatment	15.7 (13.5 to 17.9)	20.4 (17.4 to 23.4)	-4.7 (-7.6 to -1.8)	
12 months	14.5 (12.8 to 16.2)	18.4 (15.7 to 21.2)	-3.7 (-6.3 to -1.1)	
Co-primary outcomes				
Self-efficacy pain (10–100, 100 = high)†				0.001
Baseline	55.4 (50.3 to 60.6)	60.9 (55.7 to 66.4)		
Post-treatment	65.9 (61.7 to 70.0)	61.0 (55.3 to 66.7)	8.2 (2.1 to 14.2)	
12 months	67.8 (62.4 to 73.3)	61.5 (55.8 to 67.3)	9.1 (3.4 to 14.8)	
Self-efficacy symptoms (10–100, 100 = high)†				< 0.001
Baseline	64.2 (59.8 to 68.6)	66.6 (61.2 to 72.1)		
Post-treatment	74.3 (70.9 to 77.7)	68.5 (62.7 to 64.4)	8.8 (3.0 to 14.6)	
12 months	73.3 (68.9 to 77.6)	62.8 (56.4 to 69.1)	13.1 (6.7 to 19.3)	
EAC processing (1–4, 4 = high) †				< 0.001
Baseline	2.7 (2.5 to 3.0)	2.8 (2.6 to 3.1)		
Post-treatment	3.2 (3.0 to 3.4)	2.9 (2.7 to 3.1)	0.4 (0.29 to 0.6)	
12 months	3.1 (2.9 to 3.3)	2.9 (2.6 to 3.1)	0.3 (0.02 to 0.5)	
EAC expression (1–4, 4 = high)†				0.191
Baseline	2.6 (2.4 to 2.9)	2.6 (2.4 to 2.8)		
Post-treatment	3.0 (2.8 to 3.2)	2.8 (2.6 to 3.0)	0.2 (-0.02 to 0.4)	
12 months	2.9 (2.7 to 3.1)	2.8 (2.6 to 3.1)	0.04 (-0.2 to 0.3)	
Secondary outcomes				
Pain (0–10, 0 = no pain)**				0.064
Baseline	4.7 (4.1 to 5.3)	4.6 (3.9 to 5.3)		
Post-treatment	4.6 (4.1 to 5.2)	4.9 (4.1 to 5.7)	-0.4 (-0.97 to 0.22)	
12 months	3.9 (3.3 to 4.5)	4.5 (3.8 to 5.1)	-0.6 (-1.28 to 0.02)	
Fatigue (0–10, 0 = no fatigue)**				0.002
Baseline	5.2 (4.5 to 5.9)	4.9 (4.1 to 5.7)		
Post-treatment	4.8 (3.9 to 5.7)	5.2 (4.4 to 6.1)	-0.8 (-1.5 to -0.2)	
12 months	4.1 (3.3 to 5.0)	4.9 (4.1 to 5.7)	-1.1 (-1.8 to -0.4)	
PGA (0–10, 0 = no activity)**				0.069
Baseline	4.6 (4.0 to 5.1)	4.5 (3.9 to 5.2)		
Post-treatment	4.5 (3.9 to 5.0)	4.8 (4.0 to 5.5)	-0.3 (-0.89 to 0.23)	
12 months	3.8 (3.2 to 4.4)	4.5 (3.9 to 5.2)	-0.7 (-1.38 to -0.05)	
Self-care ability (0–10, 10 = very good)**				< 0.001
Baseline	7.0 (6.4 to 7.6)	6.9 (6.3 to 7.4)		
Post-treatment	7.7 (7.1 to 8.3)	6.4 (5.8 to 7.0)	1.2 (0.7 to 1.7)	
12 months	7.7 (7.1 to 8.3)	6.6 (6.0 to 7.2)	1.0 (0.5 to 1.6)	
Wellbeing (0–10, 10 = very good)**				< 0.001
Baseline	6.5 (6.0 to 7.0)	6.3 (5.9 to 6.8)		
Post-treatment	7.0 (6.5 to 7.5)	6.2 (5.6 to 6.7)	0.8 (0.2 to 1.3)	
12 months	7.4 (7.0 to 7.9)	6.7 (6.2 to 7.2)	0.6 (0.1 to 1.2)	

* Adjustment for the baseline mean values and gender, age, disease duration, education, and civil status, ** Five repeated measures at baseline and follow-ups, † Measured once at baseline and follow-ups, GHQ = General Health Questionnaire, EAC = Emotional Approach Coping, PGA = Patient global assessment of disease activity

6. Discussion

6.1 Methodological aspects

6.1.1 Study designs

Four different study designs were used: longitudinal pre – post-test, qualitative, cross-sectional and randomised controlled design.

6.1.1.1 Longitudinal design

In this design data are collected prospectively on two or more occasions. It is appropriate for studying variable or phenomenon dynamics over time and for generating hypotheses about associations between an applied intervention and a variable (151). If no parallel control group is included, it is not possible to conclude that the changes are produced by the intervention. In our study, the design was used to evaluate possible effects of the VTP and generate hypotheses that could be further tested in a controlled trial (paper I). It was also used to test the responsiveness of the EAC (paper III).

In prospective studies the number of measurements and follow-up duration varies. The latter is usually more than three and seldom more than 15 months when evaluating psychosocial interventions months (see Table 1). A main issue in our study was to evaluate if the VTP had any long-term impact on participants' health and wellbeing. We expected that integration of new coping strategies in participants' lives would take some time. Therefore follow-up duration could not be too short. At the same time, longer time before the follow-up assessments increased the risk that other events could influence participants' lives. Balancing these considerations, the follow-up time was set to 12 months.

6.1.1.2 Qualitative design

This design allow for in-depth descriptions of participant perspectives and a broader understanding of how they make sense of their experiences (181). We used focus groups to explore *how* the participants experienced the VTP in terms of its possible influences on their wellbeing and coping behaviour and the processes by which these influences arouse (paper II). Qualitative focus group interview is a common method of data collection when the aim is to evaluate strengths and weaknesses of a program (182;183). Following up the quantitative data collection in the pre – post-test study by qualitative focus group interviews, enabled participants to speak for themselves and added descriptive and explanatory data to the statistical data, and thus deepened our understanding of how the participants created meaning from their experiences (181).

6.1.1.3 Cross-sectional design

The cross-sectional design is considered a practical and relatively easy way to collect large amounts of data with moderate resources because data are collected at a single time point only. It is appropriate for describing the status of a phenomenon or investigating the associations between phenomena at a fixed time-point (151). Because the respondents are contacted only once, the chance of a high response rate increases. A limitation is the lack of opportunity to study the stability of findings over time.

In our study this design was used to test the factor structure, internal consistency, construct validity and the applicability of the EAC (paper III). For this purpose the EAC was tested together with other scales at the same time point and a cross-sectional design was considered appropriate (174).

6.1.1.4 Randomised controlled design

This design is considered the 'gold standard' for evaluating intervention effects (184). In high quality RCTs, participants are randomly allocated to intervention or control arm, with the trial arm concealed to both participants and researchers if

possible. The study should be appropriately powered to find significant treatment effects, and intention to treat analysis should be performed. The participants should also be representative of the population for which the results are intended to be valid (185).

There are major obstacles to performing high quality non-pharmacological RCTs. Placebo or sham therapy is practically impossible, making blinding difficult or most often impossible. Participants will therefore know which arm they are allocated to and what the preferred intervention is. Being allocated to 'routine care' may be a disappointment and lead to a performance bias. Also, contamination may be introduced if the control group participants try similar interventions for themselves. The intervention group will receive considerable attention that may exaggerate the effects. Because the participants may be reluctant to being allocated to the control group, recruitment is often difficult, resulting in a selection bias (186). Therefore the studies may often be considered as *pragmatic*, i.e. they are conducted in a real-world context with a real-world spectrum of participants, when intending to evaluate whether the intervention improves clinical outcomes.

Despite these obstacles and limitations, we conducted a pragmatic randomised controlled trial to evaluate VTP effects. With the intent to compensate for negative effects from being allocated to routine care only, control group participants received a CD with mindfulness-based home exercises for individual voluntary use. They were also informed that they would be invited to VTP participation after completed data collection. While VTP participants or group facilitators could not be blinded, both assessors and the statistician, who conducted the primary analyses, were blinded for group allocation.

6.1.2 Study samples

The extrapolation of results from the study sample to the population of interest depends on the representativeness of the sample (187). Selection of study sample and sample sizes will therefore influence the external validity of the study. Group

interventions, such as the VTP, demand much more time and efforts from the participants than taking medications, and interventions that address emotional reactions to the disease and its consequences can prove challenging (188;189). Recruitment may therefore be difficult, and it is often necessary to approach a large amount of people to include sufficient number of participants in a trial, especially if the trial includes a control group. Thus, in pragmatic trials, which aim to represent how an intervention operates in reality outside the research setting, representativeness may be difficult to obtain and self-selection may be a source of selection bias.

6.1.2.1 Sample included in the pre – post-test and the focus group studies

The implementation of VTP groups at the rheumatology departments started in January 2003. Patients who visited the rheumatology outpatient clinics and the rheumatology in-patient wards were informed about the VTP courses and invited to attend open information meetings. People who were interested after the information meetings, enrolled in the VTP. Persons who met the inclusion criteria, i.e. confirmed rheumatologic diagnosis; age 20 years or older and good understanding of Norwegian language, were then asked to participate in the study. Thus, a selection bias of particularly interested persons may have been introduced.

Patients with a wide range of inflammatory and non-inflammatory rheumatologic diagnoses were recruited for the study. The majority had RA, and the percentage distribution of diagnoses was probably representative for patients visiting each department. An exception was the two departments that, due to a large amount of referrals of FMS patients to their clinics, recruited only patients with FMS.

The sample had a skewed gender distribution. The proportion of men was relatively lower than the gender distribution of the diseases, which gives reason to ask whether the VTP attracts more women than men. The RA patients were slightly younger compared to other samples drawn from the Oslo RA Register in the same time period, whereas the AS patients were comparable to the AS Register. Our sample had slightly shorter disease duration and was less disabled than the register patients (15;40;190).

However, the levels of pain, fatigue and psychological distress were relatively high, indicating that the included patients might have been in need for the intervention, and thus had a potential for improvement.

Further, because we included only people with good understanding of Norwegian language, people with non-Norwegian cultural background were probably underrepresented. Recognising that there is a relatively large group of immigrants with rheumatic diseases in Norway, adaptation of the VTP to these groups of patients should be investigated in further research.

Participants in the focus group interviews, i.e. the first ten VTP groups, did not differ significantly from the whole sample in any variables. However, the objective of the qualitative study was not to generalise the results, but to get a deeper understanding of the participants' experiences. The criterion of representativeness is therefore not applicable. Instead, to illuminate different understandings and meanings, participants should reflect a range of the total study population ("purposive sampling") (181;183;191). In our focus groups the proportions of males and females were similar to the whole sample. They represented a range of ages and disease duration; they were single and married, working and non-working participants.

Number of participants in qualitative studies is normally not predefined. Sampling usually stops when a thorough understanding of the phenomenon under study has been reached (often called "saturation") (191). Our inclusion stopped when we had interviewed ten groups, which had been facilitated by different group leaders, and which represented five rheumatology departments. When we read the transcripts from these interviews, we considered that the content was sufficient to give us a broad understanding of participant experiences.

6.1.2.2 Samples included in the study of measurement properties of the EAC

Estimates of validity are dependent upon the nature of the people being measured, and to a greater or less degree, the circumstances under which they are being assessed

(174). The sample included in this validation study was consecutively recruited from patients who attended regular consultations at rheumatology inpatient, outpatient or day clinics at four different rheumatology departments. In addition, two samples of patients attending four VTP groups and five diagnosis-specific SMP courses were included in both the cross-sectional validation study and the responsiveness study. There was a slightly higher proportion of IA patients and men in the consecutive sample compared to the two other samples, probably reflecting the patients attending regular rheumatology consultations at these clinics. In the sample included in the responsiveness study, the participants attending the VTP were significantly younger than the participants attending the SMP. The SMP did not include RA patients and had a higher proportion of FMS patients, limiting the representativeness of this sample.

Although there are limitations to representativeness of the samples included in this study, the total sample reflected the approximate distribution of rheumatologic diagnoses among patients attending regular consultations at rheumatology departments in Norway. They were comparable with the sample included in the previous pre – post-test study as regard to age and disease duration. Because the EAC is a generic questionnaire, the variety of diagnoses should not influence the results. However, the results may have been influenced by other patient characteristics, such as levels of symptoms, disease severity and other health related outcomes, which were not measured in this study. The relatively small samples may also limit the interpretation of the results, especially in the responsiveness study. Further testing of the EAC based on larger samples is therefore recommended.

6.1.2.3 Sample included in the randomised controlled trial

Based on the results from the pre – post-test study, only patients with inflammatory rheumatic joint diseases were included in the RCT. Participants were recruited from three rheumatology departments in south-eastern Norway between March 2007 and June 2009. The VTP was already implemented at the departments, and there were waiting lists for participation. When we asked people on the waiting lists to

participate in the RCT, several refused because they did not want the risk of being allocated to the control group and having to wait another year for the intervention. We therefore approached registry patients at one of the hospitals (The Oslo RA Register and the AS Register at Diakonhjemmet Hospital, see section 4.4.3), who did not regularly visit the clinics, and whom we assumed had not heard about the VTP before. Consequently, we did not know if they needed such an intervention at the time they were approached. In addition, one of the departments that previously had included only FMS patients, accepted to recruit people with IA, who regularly visited their clinics.

A total of 814 people were invited by letter to attend the information meetings, 152 accepted the invitation and 113 attended the meetings. After having received information, 73 persons consented to participate in the study. It is likely that this sample consisted of highly motivated persons, who recognised their need for the intervention, and who were willing to invest their time and effort in participation.

As regard to age and gender distribution, the sample was comparable to samples included in other relevant studies (113;121;122;134). The sample had higher level of education than the general Norwegian population (15), but only about forty percent had paid work, which may reflect the relatively long disease duration. The work disability was close to what was found in a Norwegian cohort of RA patients with approximately the same disease duration (192), but higher than a cohort from the AS register (15). The levels of pain, fatigue and patient-reported disease activity were relatively high, but slightly lower than in the previous pre – post-test study. More than 32% of the participants were characterised as highly distressed. Considering these characteristics, the sample may be representative for those who experience a relatively high disease impact and are motivated to work on having a better life with their disease.

6.1.3 The Vitality Training Program

As outlined in section 2.3 the VTP was initially developed for persons with chronic musculoskeletal pain (143). The overall goal of the present thesis was to evaluate whether this kind of intervention could be effective also in patients with inflammatory rheumatic diseases. To adjust the program for IA patients, we collaborated with two persons who had long-term experience of living with RA. We also tested the program in two pilot groups and made further adaptations according to responses from the participants. An example of alteration from the original program is that the topic 'sorrow' was included. The program was also shortened from 12 to 10 sessions to make it more feasible.

A critical issue is whether the VTP was carried out in the same way in all the groups. To ensure that all topics and methods were implemented as similar as possible, we prepared a manual with thorough descriptions of the program. Equally important was the training of the group facilitators in a comprehensive one-year education, comprising six three-day workshops, plus home assignments and completed by a practical examination. However, group processes will always be influenced by the facilitators' personal qualifications as well as the interactions between group participants, and therefore some variations between the groups are likely to exist.

In the RCT (paper IV), our primary goal was to investigate whether the VTP had added value beyond routine care. Concerns about the routine care control group have been raised in section 6.1.1.3. We realise that routine care do not control for the effect of the attention that the intervention group receives. However, we consider the attention and the social support from the group facilitators and other group participants to be embedded in the VTP and part of what we are evaluating. To reduce a possible negative effect of no attention, the control group received a CD with mindfulness-based home exercises for voluntarily use. Because we did not expect the CD to have similar effects as group participation, we did not ask them to register their use of it. Thus, we have not been able to control for possible effects of the CD. However, informal feedback from control group participants indicates that

they had not experienced the usefulness of the CD before they participated in the VTP.

An alternative to routine control might have been to compare the VTP to other group interventions, such as "Living a Healthier Life" ("Å leve et friskere liv") or a CBT intervention, to evaluate the comparative effectiveness of these interventions. This is an issue for further studies.

6.1.4 Methods of data collection

6.1.4.1 Self-reported measures

All data in this study, except for age, diagnosis and disease duration, were self-reported and collected by questionnaires. The basic assumption of patient-reported data is that knowledge about subjective experiences, such as emotional wellbeing, pain and fatigue is best obtained by asking the person of interest. There is of course a risk of response bias, i.e. respondents may either underreport or overestimate their symptoms, and thus the effect of interventions. However, research comparing physician-reported and patient-reported assessments has concluded that improvements in signs and symptoms of active RA in randomised, placebo-controlled trials is equally or better reflected by patient-reported measures (193-196). The strength of the self-reported outcomes is that they reduce the effect of observer bias. A limitation in this study may be that the core set for disease activity measurement was not included. However, we did not expect that the intervention would influence disease activity.

Completing questionnaires may be time consuming and strenuous, and the quality of the data may be influenced by the length and order of the questionnaires. Thus we had to balance the need for information with making the questionnaire reasonably short. We also considered the order of the different questionnaires included in the comprehensive package. Some has recommended that the broader and less sensitive questionnaires should be placed before the diseases specific and the more sensitive

questions (197), whereas others have not found any evidence of order effect when different measures are combined (198). In this project we used two different orders. In the pre – post-test study, the questions related to the diseases were placed first. In the RCT, we started with the outcomes that were measured five times and continued with the questions related to emotions and self-efficacy, because we wanted to introduce the participants to the most relevant outcome measures first. The response rates were relatively high in both studies and did not seem to be influenced by the order of the questions. It is not possible to say if answering questions about psychological distress and symptoms first may have influenced the participants' further answers about for example emotional responses and self-efficacy.

6.1.4.2 Telephone interviews

The mode of data collection has been found to influence patient responses (199;200). Feveile et al found that the overall response-rate was similar for questionnaires and telephone interviews, but the numbers of missing items were lower in telephone interviews. For health assessment items extreme response categories as well as more positive reporting were used more frequently among telephone respondents (200).

The rationale for using telephone interviews in our study was to increase the response rate. Because we wanted to collect data five times at two-week intervals at each assessment point, we assumed that the burden on patients would be less if they were called, than if they were asked to fill in and return questionnaires. We may consider if a response bias towards a more positive rating may have occurred. Because of the frequency of the interviews, there is also a risk that the responses are influenced by the respondent's memory, a recall bias. However, the interviewers emphasised that the questions should reflect the respondent's condition "during the last two weeks" (GHQ-20) or "during the last week" (NRSs).

6.1.4.3 Focus group interviews

In qualitative interviews, understanding the participant's context is a central concern. The interviewers therefore need to identify their own context and predispositions in

order to understand how their own views and beliefs may influence the interactions they have with the participants (181). In our study, three different interviewers moderated the focus groups. All were experienced interviewers with good knowledge of the VTP, who had not facilitated any of the groups. The interviewers had discussed their predispositions in advance, such as being influenced by their own interests in and previous experiences from the VTP.

A general problem in qualitative studies is that patients might be liable to say positive things in order to please the interviewer. The interviewers came to an agreement on aiming to create an open conversation, in which all participant views could be comprehensively explored and to be particularly responsive to any critical issues as they arose within the group. The group facilitators did not take part in the interviews, and the participants were encouraged to elaborate on how interactions with the group facilitators had influenced their experiences. Focus groups explicitly use group interaction as a part of the method. It can also be objected that group interviews favour the most articulate persons, and group norms may silence individuals with divergent opinions. However, studies have shown that focus groups encourage participation from people who are reluctant to be interviewed on their own or who feel that they have nothing to say, and that group processes can help people explore and clarify their views in ways that would be less easily accessible in one to one interview (183).

Interviewing is an evolving process during which the interviewers acquire new insights into the phenomenon of study that can subsequently influence follow-up questions and may narrow the focus in succeeding interviews (201). This might have happened in our study, which included ten group interviews. However, the fact that three different interviewers conducted the interviews reduced this risk of selective awareness. Also, the semi-structured interview guide ensured that the same topics were explored in each group. To ensure confidentiality, no names were used during the interviews.

6.1.5 Outcome measures

When evaluating effects of interventions in clinical trials, the outcome measures must be able to detect a meaningful or clinically relevant change over time. This ability is referred to as the instruments' responsiveness (169;177). An important criterion for choosing instruments in order to detect change in physical or emotional health status is whether they are generic or disease-specific. Generic measures seek a broad perspective that is not specifically related to the particular disease. Therefore, they allow investigators to compare health status across different diseases and interventions. Disease-specific measures focus on aspects of health that are relevant to a particular group of patients. Thus, they provide the opportunity to tap more precisely intervention-related improvements in domains of health that may have been deteriorated due to the disease (176;177). Studies have indicated that in RCT's with a true underlying effect, specific instruments are more responsive to change than generic instruments (176).

In our studies, we included individuals with various rheumatic diseases. We therefore had to choose instruments, which were broad enough to capture aspects of health that are common across the different diagnoses, and sensitive enough to detect clinically relevant changes in the domains that the VTP was most likely to impact. Strengths and weaknesses of the main outcome measures are discussed below.

6.1.5.1 The General Health Questionnaire (GHQ)

The GHQ is a widely used screening instrument for detecting psychological distress. Unlike other screening instruments for psychological disorders, the GHQ is balanced between positively phrased items, indicating psychological health, and negatively phrased items, indicating psychological distress. The respondents are requested to compare their current status with what they consider as their 'normal' condition. There are several versions of the GHQ. The 20-item version, which we have used in our studies, has been validated in a Norwegian sample of accidentally injured trauma patients. It has proved to provide acceptable values for sensitivity and specificity to

detect serious psychological distress at a cut-off between 23 and 24 (sum score) (160;161). The GHQ-20 has also been found to be responsive to changes in mental health status following stressful events and during the course of rehabilitation, using a Likert scoring procedure (160;161).

A possible limitation concerning the use of the GHQ in persons with chronic somatic diseases is that they may find it difficult to consider what their 'normal' or 'usual' condition is, especially when their condition is fluctuating. Some persons will tend to compare their current condition to how they perceived their health status before they got ill, and hence, they will always be under a certain distress. One may also assume that what individuals consider as 'normal' may change as they adjust to the distressing experiences from the disease. Careful interpretation of the scorings is therefore required.

6.1.5.2 The Arthritis Self-Efficacy Scale (ASES)

The ASES is an arthritis-specific instrument, comprising three subscales; self-efficacy pain, self-efficacy function and self-efficacy other symptoms (85). The instrument is found to have appropriate validity and reliability in arthritis patients and is frequently used as an outcome measure in self-management interventions, in which self-efficacy believes are found to be modifiable (109).

Although the VTP was not designed to influence participants' self-efficacy believes directly (see section 2.2.2 and 2.3.1), we considered the ASES to be a relevant instrument to measure *if* the VTP could strengthen the participants' self-efficacy and for comparing the effects of the VTP with other interventions. Based on the results from the pre – post-test study, we included the ASES as a co-primary outcome in the RCT. Because we did not expect the VTP to influence physical function, we omitted the self-efficacy function subscale.

The ASES is found to be correlated with favourable health status changes (85;90), and consequently, we might have included it as a mediating variable rather than an

outcome. However, in our study we wanted to measure the direct effects of the VTP on perceived self-efficacy and therefore included it as an outcome.

6.1.5.3 The Emotional Approach Coping Scale (EAC)

The rationale for including the EAC is outlined in section 2.2.4.1, and the measurement properties in Norwegian patients with rheumatic diseases were evaluated in paper III. Some limitations of the EAC need to be mentioned. First, the EAC was not evaluated for test – retest reliability in our study, which is recommended for the use of EAC in further studies. However, satisfactory test – retest reliability and inter-judge reliability have been documented in other studies (83;101). Second, an underlying assumption is that individuals are aware about how they relate to their emotions and are able to report that properly. It may be hypothesised that when individuals have completed an intervention that focus on awareness and expression of emotions, they may have changed the way they perceive their ability to process and express emotions. This may influence the instrument's responsiveness to change. However, in our validation study (paper III) the EAC was found to be responsive to change after the VTP. Third, the EAC items are of a general nature and do not address specific emotions. Thus, the instrument does not give any information about the more specific emotional reactions that may be relevant responses to chronic diseases, such as for example anxiety, anger or sadness (101).

6.1.5.4 Visual Analogue Scales (VAS) and Numerical Rating Scales (NRS)

In paper I, VASs were used for measuring pain, fatigue, patient global disease activity, self-care ability and overall wellbeing. The VAS is a 10-cm horizontal line anchored with two extremes at the ends. Respondents are asked to make a mark across the line at the point that best indicates to which degree they experience the actual item (e.g. pain or fatigue). The distance in mm between zero and the mark gives a number that quantifies the respondent's perceived severity of the item. The VAS is a valid, reliable and widely used measure for subjective experiences, but the

scale has some limitations (202-204). Meaningful use of the VAS requires a cognitive understanding of the linear representation of a phenomenon. Hence, individuals with poorly developed numerical, graphical or verbal skills may have problems with the scoring. The VAS can only be administered in a written form, which is a limitation for visually impaired persons, and it is not applicable in telephone interviews. (203;205). Further, the VAS assumes that the examined phenomenon may be expressed as a linear function. This concept is debatable and the interpretation of VAS scores has therefore been discussed (206;207). Additionally, possible measurement errors may occur because photocopying may alter the length of the VAS line and measuring the distance may be inaccurate (208).

The NRS is also a 10-cm horizontal line anchored with two extremes at the ends. Unlike the VAS, the NRS has fixed boxes, numbered from zero to ten, and the respondents are asked to tick the number that best indicate their condition. Hence, NRSs can easily be used by visually impaired persons and in telephone interviews. Comparisons of VAS and NRS for measuring pain have documented similar clinimetric properties. However, the NRS seems to have better sensitivity and is the most preferred scale by the respondents (204;205). Consequently, we replaced the VAS with NRS in the RCT (paper IV).

6.1.6 Data analyses

6.1.6.1 Statistical methods and analyses of quantitative data

All outcome variables were continuous and results were reported as mean values with 95% CI of the differences. The 95% CI indicates the interval containing the true value with 95% probability; thus showing the uncertainty of the estimate and is considered to provide more useful information than the p-value (187). Because p-values are frequently used when reporting statistical effects of interventions, we have also reported the p-values for changes (paper I and III) and differences between groups (paper IV). In order to interpret the p-values, the level of significance (α-level) was set at < 0.05 in all studies, which means less than 5% risk of making a type 1

error (i.e. rejecting the null-hypothesis when it is actually true). In paper I, the multiple measurements (i.e. including eight outcome variables) may have increased the risk of a type I error, and thereby have influenced the validity of the results.

In papers I and III, paired t-tests were computed to examine changes in outcome variables from baseline to follow-ups. Paired t-tests are used to compare the means of two groups of measurements, and are only appropriate when there is just one observation for each pair of variables (e.g. before and after an intervention). T-tests are not suitable to compare multiple observations or to adjust for covariates. If values are missing, the mean for that individual will not be calculated. The t-tests assume that the variables are normally distributed.

A superior choice of method when comparing groups at different time points is a general linear model, such as repeated measures ANOVA or mixed model repeated measures. We therefore used the mixed model repeated measures for estimating treatment effects (i.e. between-group differences) in the RCT. This model includes the interaction of treatment and time and allows adjustment for baseline values of covariates. This type of analysis is robust to missing values, because the patients are included at time points with non-missing values only. We applied a parametric bootstrap procedure to ascertain the robustness of the findings. (A number of patients, equal to the number included in the sample, were drawn from the original data and replaced. Estimates from these data were recalculated, and this process was repeated 5000 times). The model assumptions were assessed using Cook's d (i.e. measuring effect of deleting a given observation, for example outliers) and Covratio statistics (i.e. measuring the effect of observations on the covariance matrix of the parameter estimates) for individuals as well as for the estimated covariance.

To compare a particular intervention's different outcomes independent of the measuring units, the effects can be standardised in units of standard deviation, calculated as change scores within a group or between-group differences. The resulting statistical measure is known as the effect size (ES) index (169;177). Cohen has defined thresholds to interpret the magnitude of the ES as *trivial* (< 0.20), *small*

(0.20 – 0.49), *moderate* (0.50 – 0.79) and *large* (more than 0.80) (170). In paper I and III, ES for the change scores were calculated as SRMs by dividing the mean change for each outcome measure by the SD of the change score. In paper IV, the treatment effect sizes were calculated as the adjusted between-group difference in scores divided by the pooled SD of the baseline scores for each variable (Cohen's d) (168;169).

In paper III, evidence for the existence of the two EAC subscales was assessed by PCA with varimax rotation (172). Components with *eigenvalues* greater than one were considered potentially important. Eigenvalue is an index of the amount of variance accounted for by each factor (174). Because the factor structure had been determined in previous studies, we might instead have used a confirmatory factor analyses to compare the Norwegian version by the original American version of the EAC (174;209).

Internal consistency was assessed by item-total correlations and Cronbach's alpha. The usual rule of thumb is that an item's correlation with the total score should be above 0.20, and that items with lower correlations should be discarded (174). A Cronbach's alpha value of 0.70 is considered acceptable for a scale to be sufficiently reliable for use in groups of patients (174;209). To evaluate the construct validity, Pearson's correlation coefficient was used to calculate the correlations between the instruments. Correlations less than 0.5 were considered low (174;187).

A limitation of the responsiveness statistics in paper III is that we only assessed the change scores and p-values, in which "real change" is not distinguished from measurement error. More appropriate statistical methods would have been either the Guyatt responsiveness statistic or the receiver operating characteristic curves (ROC analyses) (210;211). However, because we did not collect test-retest data, the calculation of the responsiveness statistic that takes into account the score variation in patients who are stable, was not possible. Further, the absence of an external criterion related to whether patients had an important improvement in coping limited the scope for ROC analysis in this study.

6.1.6.2 Qualitative analyses

In order to establish trustworthiness in qualitative content analysis, the process of the analysis should be described in sufficient detail, so that the readers have a clear understanding of how the analysis was carried out and its strengths and limitations (180). The process of our data analysis is described in section 4.8.2., and examples of quotations used to form the categories are given in table 7.

Credibility of the findings deals with how well categories and themes cover the data (201). Our data comprised 10 focus groups, each interview ranging from 10 to 34 pages of written texts. Identifying codes, simplifying the data and forming more abstract categories that reflected the content in a reliable way was therefore a great challenge. Two researchers independently carried out the initial analysis and then compared and discussed the results in order to illuminate differences in interpretations. Further, the analysis was discussed with a third experienced qualitative researcher who had no prior knowledge about the VTP, and therefore could question our interpretations in a constructive way. We also had the opportunity to discuss coding issues and labelling of categories in a group of co-researchers, which is a form of content validation (201).

6.2 Main results

6.2.1 Participants' experiences of the VTP

The VTP had influenced the participants' self-understanding and helped them integrating their identity as being both ill and healthy. For some participants the most important experience had been to recognize themselves as being more than the disease. For others it had been important to accept the impact of their illness and the accompanying limitations. The program topics and the various methods had given them the opportunity to become more aware of and recognize their emotions and reflect upon the meaning of these emotions in relation to their current life situation. Participants had increased their awareness of own needs, for example the need for

setting own limits and allowing themselves to take a break without getting bad conscience. A majority of the participants emphasized that the community with others with a similar condition, symptoms and emotional reactions as themselves had been particularly important. They felt understood without having to explain their condition.

The VTP did not target predefined goals or behavior change. Participants described how change happened as a result of increased non-judgmental awareness and acceptance of their emotional experiences and habitual patterns. This is in accordance with "the paradoxical nature of change" which is outlined in section 2.3.1.2. Instead of just continuing to do what they thought was expected of them, they had begun to make choices that were consistent with their own needs and values. This was an individual and complex process that required time, and for some it had initially provoked uncertainty. An important prerequisite for daring to explore own emotional reactions and behavior patterns had been the confident relationship with the group facilitators, who had the ability to be present, pay attention to and respond to them as human beings.

Some participants described how they had tried to be optimistic and restrain their emotional reactions in order to protect themselves from negative feelings and from being a burden to others. This might initially have been a useful coping strategy, but over time it had placed heavy burdens on their bodies and caused bodily tensions. Recent studies have shown that limited awareness of the nuances of emotions and lack of ability to recognize and express emotions properly, may leave these emotions unresolved, increase emotional distress, inhibit health promoting behavior and compromise communication with health care providers (6;60;83). In contrast, actively processing and expressing emotions can decrease distress, create opportunities for social support, enhance closeness with others and improve adjustment to chronic disease over time (6;83;94).

Two sets of emotions were particularly highlighted in this study; frustration and anger, and sadness and sorrow. These were feelings that patients had tried to avoid or

not pay attention to, because they had perceived them as negative and unpleasant. To acknowledge that anger could be a response to stretching too far, or not paying attention to their own needs, had relieved bodily tensions and released energy. Likewise, recognition of sorrow for not being able to work or having lost health might have been the first step towards accepting how profound these losses were, and the beginning of a reorientation process towards finding new and meaningful life activities.

Most participants described the recognition and expression of emotions as positive. However, a few were reluctant to disclose their feelings in a group setting. The focus on emotions might initially have been unfamiliar, and the intensity by which feelings were experienced might have been surprising and sometimes unpleasant or frightening. It may be hypothesized that participating in a group intervention with an explicit focus on emotions will distress persons with an avoidance oriented coping style or persons who have difficulty in identifying and describing emotions (in psychological terms referred to as *alexithymia*) (212). However, only a very few participants expressed negative experiences, such as the group being too emotional and too focused on mental problems. A few participants also expressed that they had been ambivalent to disclosing personal feelings because they had been afraid that they could not be handled by the group.

People with FMS particularly addressed the importance of being recognized as a credible patient. Although there were individual variations, the majority of participants with FMS had struggled for years to prove that they were ill and to obtain a recognized diagnosis. In order to be believed and taken seriously they had had to focus more on their symptoms than on the healthy part of themselves. The lack of understanding had been accompanied by feelings of shame, inferiority, being misunderstood and disbelieved. For some, the experience of distrust had led to isolation and a feeling of loneliness. These descriptions of FMS patients' experiences of invalidation agree with other studies reporting that FMS is a low prestige diagnosis (213), and that the patients feel stigmatized and not taken seriously (57;214). During

the VTP, they had been allowed to express these feelings, and the invitation to participate in the VTP had legitimized and acknowledged their status as credible patients. These findings illuminate the importance of group interventions for FMS patients, but do not explain why we did not find any improvements in the FMS group in the pre – post-test study (paper I). Although the moderators of the focus group interviews encouraged participants to express divergent opinions and experiences, group norms may have covered individual differences. One to one interviews might have given more in-depth understanding of these individual variations.

Because the interviews were conducted only two weeks after the VTP was completed, participants may have exaggerated the benefits. Other aspects might have been discussed if they had experienced over time whether participation in the VTP had affected their lives. Finally, we do not know whether those who did not take part in the focus groups would have had other and more critical comments.

From these focus group interviews we concluded that the VTP had influenced participants' emotional wellbeing and adjustment to their illness. Disease symptoms, such as pain and fatigue were not particularly addressed in the interviews. Instead participants seemed to have changed their focus away from symptoms to how they could manage their situation by accepting and recognizing themselves as being both ill and healthy, recognizing their emotions and be more aware of their own needs. The beneficial influences seemed to have been reinforced by being part of a supportive community and by the explicit focus on emotional topics and use of awareness exercises.

6.2.2 Measurement properties of the EAC in Norwegian persons with rheumatic diseases

An instruments' validity can generally not be proved by a single study. Validity concerns the *degree* of confidence we can place on inferences we make about people based on their scores from the scale (174). The results from our study show that the EAC has evidence for data quality, internal consistency and validity. Further,

participation in the VTP improved emotional processing and emotional expression in patients with various rheumatic diseases, indicating that the EAC scales may be responsive to change. A major limitation of the study is that we did not assess test-retest reliability, and this is recommended in future studies.

The EAC was constructed to measure a concept of active, approach-oriented emotion-focused coping. The measurement properties of the EAC have previously been extensively assessed in samples of healthy students and women with breast cancer (101;102;104;215), but not in persons with rheumatic diseases. The quality of the data obtained from our studies would therefore depend on the relevance of the items for people with arthritis. The high response rate and low levels of missing data indicate that the EAC in general is acceptable and applicable. The PCA supported two subscales, emotional processing and emotional expression. Two of the items, "I realize that my feelings are valid and important" and "I acknowledge my emotions" loaded satisfactorily on the emotional processing factor, but might as well have contributed to a third factor. These two items had the lowest item-total correlations and highest number of missing values, reflecting that they may have been more difficult to interpret than the other items. They also had a skewed distribution towards high scores, which may reflect a high threshold for saying that one's emotions are not valid and acknowledged. The skewed distribution also produced a ceiling effect. Consequently, these items limit the content validity, reliability and responsiveness of the emotional processing subscale.

In accordance with findings in previous studies, both EAC scales have high internal consistency (101). Using the proposed criteria for Chronbach's alpha of between 0.70 and 0.90; the high alpha value for the emotional expression scale may indicate redundancy of some of the items (174). However, this criterion has been discussed. Terwee and colleagues give a positive rating for Chronbach's alpha between 0.70 and 0.95 (209). A shorter version of the EAC, comprising two four-item scales has been tested, but the eight-item scales were found to have slightly higher reliability (101),

which was the reason for choosing the longer version for this cross-cultural adaptation.

The hypothesis that the EAC scales would be positively related to the approach-oriented items in the BACQ and uncorrelated with the avoidance-oriented items was supported. The inverse correlation between emotional expression and the GHQ-20 scores supports the hypothesis that the construct of emotional expression is not interfered with distress-laden content. Taken together, these findings correspond with previous studies, which have concluded that emotional approach coping is conceptually different from passive, avoidance-oriented coping and emotion-focused coping strategies related to distress (83;101). To further assess construct validity, the EAC should be compared with other scales measuring constructs of approach/avoidance-oriented and active/passive coping.

Responsiveness is the ability of an instrument to measure change if it has really happened. We hypothesised that the VTP, which explicitly addressed emotional topics and encouraged non-judgemental emotional awareness and sharing of emotional experiences, would increase emotional processing and expression. We therefore assessed the responsiveness of the EAC in four VTP groups. Additionally, we tested the EAC in a one-week SMP intervention, which we assumed would not produce significant changes in the EAC. As hypothesised, scores in both EAC scale increased significantly after the VTP. However, the change in emotional processing (mean change 0.27, $p < 0.05$) was relatively lower than the change in emotional expression (mean change 0.37, $p < 0.001$), which may be due to the high baseline scores and the ceiling effect of two items in the emotional processing scale. Previously, few studies have examined EAC as an outcome in interventions (215-218). Considering the limitations of the responsiveness statistics outlined in section 6.1.6.1, the small number of patients and the short follow-up period, the results relating to responsiveness in this study must be interpreted with caution. Further studies based on larger samples and longer follow-up periods should be conducted.

However, based on these preliminary findings we decided to include the EAC as an outcome measure in the RCT.

It may be questioned whether the EAC is a mediator of other effects, such as psychological distress, rather than an outcome, and thus should be considered a process measure. To get an indication of the mediating effects of the EAC, we tested if changes in the EAC scales were associated with changes in the GHQ-20 and found that increasing scores in emotional processing were associated with reduction in GHQ-20 in VTP participants. These associations need to be further explored in larger samples.

6.2.3 Clinical effects of the VTP

Improvements from participation in the VTP were initially evaluated in the pre – post-test study (paper I) and effects were further investigated in the RCT (paper IV). The RCT confirmed our findings in the pre – post-test study. Persons with inflammatory rheumatic joint diseases showed reduced psychological distress and fatigue and enhanced self-efficacy, self-care ability and overall wellbeing after VTP participation compared to routine care plus a mindfulness CD for individual voluntary use. At one-year follow-up, the number of persons with serious psychological distress (> 23) in the VTP group was reduced from 13 to 2, compared with a reduction of from 10 to 8 in the control group. Furthermore, participants' acknowledgement and understanding of their emotions (emotional processing) was increased.

In addition to the IA patients, the pre – post-test study included persons with FMS. The reason for not including FMS patients in the RCT was that no significant improvements were found in any variables in this group. IA diagnosis was the main predictor of change in psychological distress. These results differ from the first study of the VTP in persons with chronic musculoskeletal pain, including FMS, which documented significant reduction in psychological distress one year after completion (11). The differences may be due to a selection bias or small samples; or they may

indicate that other factors than diagnosis may have influenced the results. However, our results are in accordance with a review of non-pharmacological interventions in patients with FMS, which concluded that the evidence for effects in symptoms and psychological distress is limited (123). The review suggests that specific subgroups of FMS patients with relatively high levels of psychological distress can benefit from tailored CBT interventions offered at an early stage of the disease. Living with pain over a long period of time without access to relevant treatment may lead to development of maladaptive patterns of coping behaviours that may be hard to change. This seems to be supported by the findings in our qualitative study, in which participants with FMS described how they had struggled for years to be believed and taken seriously. These findings indicate that future studies should investigate effects of the VTP in FMS patients with a more recent disease onset.

The most important findings in our studies are probably the long-term effects of the VTP in persons with inflammatory rheumatic joint diseases. In the RCT, significant between-group effects were maintained or increased at 12-month follow-up with effect sizes ranging from moderate (psychological distress, self-efficacy pain, self-care ability and fatigue) to high (self-efficacy symptoms). These results are in accordance with the previous VTP studies by Haugli and colleagues, who documented reduced psychological distress and increased pain coping and self-care abilities at one-year follow-up (10;11). The results differ from reported effects of most self-management and CBT interventions (section 2.2.5, table 1). In general, effects of these interventions are found to be small and tend to decrease over time (116;119). However, a few studies have documented beneficial effects on depression, anxiety and fatigue of CBT interventions tailored to patients needs in early stages of the disease (121;122). A possible interpretation of the lasting improvements in our study is that participants may have incorporated new coping strategies into their daily lives, consistent with what has been reported in the qualitative study (section 6.2.1). These strategies seem to have strengthened their abilities to respond to stressful experiences in a more flexible way and make more conscious choices, consistent with their personal values.

Some explanations may be proposed. The process-oriented nature of the VTP does not impose behaviour changes that participants may not be ready for. Rather than being targeted toward specific goal attainments, the VTP encourages non-judgmental awareness and acceptance of whatever emerges in the present moment, whether being pleasant or unpleasant (corresponding with the mindfulness practice). Participants are further encouraged to identify their personal values and resources and to find their own meaningful answers, and thus take greater responsibility for their life choices (corresponding with ACT, see section 2.2.5.3 and 2.3.1.2). This may have strengthened their sense of internal control, and may as well have been one of the mechanisms that have increased participants' self-efficacy beliefs.

Mindfulness-based interventions have become increasingly popular in western societies, including Norway, during the last decade. Although also including other elements, the basic training in the VTP consists of mindfulness-based awareness exercises. The growing body of literature on mindfulness has therefore helped us understand possible working mechanisms of the VTP. An example of these mechanisms is that one through refined awareness becomes able to observe own thoughts, emotions and bodily senses instead of being defined by them. When individuals relate to experiences (e.g. pain or emotions) without *being* them, they will in turn experience increased freedom from automatic behavioural patterns and more flexibility in how they respond (128). Mindfulness practice is assumed to reduce stress and stress-related responses and thereby increasing ability to cope with pain and disability and internal motivation for life-style changes, reducing anxiety and depression and enriching interpersonal relationships and social connectedness (219). Although research is still limited, it has been suggested that mindfulness training may positively regulate brain, endocrine and immune function. In a study comparing MBSR to a waiting list control group, significant left-sided anterior activation (patterns associated with positive emotional experiences) and increased antibody titers to influenza vaccine were found in the mindfulness group (220). Clinical studies in various populations have supported the use of mindfulness-based training to reduce anxiety and depression (134;135;221;222), and in a recent meta-analytic

review the effects were found to be rather robust and strong (127). Mindfulness practice addresses the distressing experiences that may occur in several chronic conditions, such as inflammatory rheumatic diseases and chronic pain conditions. By changing the way people relate to these experiences, mindfulness may improve general aspects of health and wellbeing (126;127;223).

In addition to the mindfulness-based exercises, the VTP explicitly addresses emotional topics, such as anger, sorrow and joy in three of the sessions. As previously stated, there is a growing body of evidence showing that recognising and expressing emotions may decrease the stressful impact of negative emotions (for example anger and self-blame) (6;82;83). More recently, the role of positive emotions, such as joy and interest, have gained increased attention as essential elements of optimal function (224-226). Positive emotions are thought to promote discovery of novel and creative action, enhance individuals' personal resources and function as a buffer towards negative experiences (224). In the VTP, participants are invited to explore and attend to both negative and positive emotions in an open, non-judgemental way. As hypothesised, the VTP participants significantly increased their emotional processing compared with the control group. Interestingly, emotional expression improved in both groups at the 12-month follow-up. The fact that the control group was interviewed on telephone four times at two-week intervals on three occasions during the control period, answering questions about emotional issues, may have influenced their perceptions of how they expressed emotions, and thus partly explain the improvements in this group.

Although there has been an increasing focus on the impact of fatigue in patients with inflammatory arthritis in recent years (19;27;32;227), only a few studies on interventions aimed at improving individuals' ability to cope with fatigue have been published. Individual and group CBT-interventions with a special focus on fatigue have been found to improve fatigue impact and coping in RA patients (112;113;122), but more studies are asked for (228). The VTP did not explicitly address fatigue. However, through mindfulness practice the participants learned to be more fully

present in their immediate experiences, without making an effort to avoid or change them. In addition, the creative exercises used in the VTP were directed at helping participants discover more of their health-promoting resources and to make choices consistent with their personal values. As described in the qualitative study, participants had become more aware of their own needs, allowing themselves to take breaks and act more in accordance with own values and choices, instead of complying to others expectations. These may have been energy-releasing processes, but the associations have to be further explored. Some studies have reported an association between fatigue and psychological distress (19;227), and it is possible that improvement in psychological distress might have mediated a reduction in fatigue or vice versa. This association needs further investigation.

There are some major limitations to the generalisability of our results. Only a small sample of the approached people enrolled in the study, which probably reflects a selection bias in the direction of particularly interested persons. Consequently, the results cannot be generalised to the whole population of persons with IA (see section 6.1.2.3). The reasons reported for not participating were multifaceted. Several were interested, but the time schedule was not suitable, some could not be absent from work, some had family obligations and some felt too ill or too healthy. For some the topics and methods in the VTP may have seemed too challenging. The problem of self-selection is common for studies of self-management and other psychosocial interventions (188;189). Motivation is important in all kind of interventions and particularly in interventions that require active participation and personal effort. The key question is how people can be reached with information at the time they are motivated and in need for this kind of intervention. The majority of participants in our studies had relatively long disease duration and high disease impact in terms of psychological distress, pain and fatigue, indicating that the VTP is most relevant for this group of patients. However, several participants asked why they had not been offered to participate in the VTP at an earlier stage, and further studies are needed to explore the effects of the VTP in persons with more recent onset disease.

Most people who enrolled in the VTP showed high commitment to the intervention. They attended between 8 and 10 sessions, and there were very few dropouts, indicating that it was feasible for those who enrolled. Since the first groups were implemented in 2003, the VTP has routinely been conducted at several rheumatology departments, and we know that there are waiting lists for participation. Thus, the intervention seems to be more feasible in clinical practice than in research. The VTP is not intended to be included in routine care, but to be a complementary intervention for people who need to strengthen their abilities to respond to the stressful experiences related to their disease. The comparative effectiveness of the VTP and less intensive interventions needs to be evaluated in future studies, and shortening of the program without compromising its content may be considered.

7. Conclusions and Implications

The studies included in this thesis have documented beneficial clinical effects of the VTP in terms of reduced psychological distress and fatigue, and increased self-efficacy and processing of emotions. The effects were maintained at the 12-month follow-up. The qualitative study of experiences from VTP participation illuminated how the participants had recognized themselves as being both ill and healthy, increased their recognition of own emotions and their awareness of own needs. The combination of program topics and methods and being part of a community where they felt recognized, seemed to have reinforced the participants' beneficial experiences. The process-oriented nature and length of the program had been important to create community within the groups. Additionally, the facilitators' abilities to be aware and responsive to the participants had been important for creating a supportive community.

The studies have provided the following answers to our specific research questions:

- Participation in the VTP significantly improved psychological wellbeing (reduced psychological distress and increased overall wellbeing), self-efficacy pain and symptoms, pain and fatigue in patients with IA. No significant improvements in any variables were found in patients with FMS.
- IA diagnosis and high fatigue scores at baseline were main predictors of reduction in psychological distress at one-year follow-up.
- The VTP had influenced participants' emotional wellbeing and coping behaviour by promoting their recognition of themselves as being both ill and healthy, increasing their recognition of own emotions and their awareness of own needs.
- The beneficial influences seemed to have been reinforced by being part of a supportive community and by the explicit focus on emotional topics and use of mindfulness-based exercises (awareness).

- The EAC had evidence for data quality, internal consistency and construct validity, but has yet to be assessed for test-retest reliability.
- Participation in the VTP improved emotion-focused coping strategies as measured by the EAC in patients with various rheumatic diseases, indicating that the EAC scales are responsive to change.
- The VTP significantly improved psychological distress, self-efficacy pain and symptoms and emotional processing, compared to a routine care control group that received a CD with mindfulness-based home exercises
- The potential for selection bias reduces the generalisability of the results. However, based on the robustness of the statistical methods, participants' high commitment to the intervention and the long-term effects, it is reasonably to conclude that the VTP may be considered a beneficial complement to existing treatments in persons with IA, particularly for those who experience heightened psychological distress and fatigue.

Some issues for further research may be suggested:

The effects the VTP and other psychosocial group interventions should be compared. Shorter versions of the VTP may also be adapted and tested. Moreover, the VTP is resource-intensive and economic evaluation should be undertaken. Within a national Norwegian context, the VTP may be compared to other inpatient and outpatient rehabilitation programs. Further studies are also needed to investigate whether certain personality factors are associated with better outcomes from this kind of intervention.

The EAC study may be considered as an initial validation study, and it is further important to evaluate the instrument's test-retest reliability. Moreover, studies based on larger samples with longer follow-up period and more appropriate statistical methods, such as Gyatt responsiveness statistics, are needed for further testing of responsiveness. There is reason to believe that the EAC may be more valid as a mediator of other psychological and health-related outcomes. Studies of the predictive validity of the EAC are therefore recommended.

Only patients with rheumatic diseases were included in the study, and the findings cannot automatically be transferred to other populations. As similar emotional responses may be recognized by patients with other chronic diseases, the program may therefore be adapted and tested in other patient groups.

In summary, this thesis has provided evidence for the health promoting effects of the VTP. It is a safe and feasible intervention that can be recommended to persons with inflammatory rheumatic joint diseases who are willing to invest time and effort in participation.

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Errata

Page 13 List of papers

The title of paper IV should be: A mindfulness-based group intervention *to reduce* psychological distress and fatigue in patients with inflammatory rheumatic joint diseases: a randomised controlled trial**.**

Page 53 Table 4: The Brief Approach/Avoidance Coping Questionnaire (BACQ) is included in *paper III*.

I

II

III

BMC Musculoskeletal Disorders

Research article

Emotion regulation in patients with rheumatic diseases: validity and responsiveness of the Emotional Approach Coping Scale (EAC)

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Published: 3 September 2009

BMC Musculoskeletal Disorders 2009, **10**:107 doi:10.1186/1471-2474-10-107

Received: 25 February 2009
Accepted: 3 September 2009

This article is available from: http://www.biomedcentral.com/1471-2474/10/107

Abstract

Background: Chronic rheumatic diseases are painful conditions which are not entirely controllable and can place high emotional demands on individuals. Increasing evidence has shown that emotion regulation in terms of actively processing and expressing disease-related emotions are likely to promote positive adjustment in patients with chronic diseases. The Emotional Approach Coping Scale (EAC) measures active attempts to acknowledge, understand, and express emotions. Although tested in other clinical samples, the EAC has not been validated for patients with rheumatic diseases. This study evaluated the data quality, internal consistency reliability, validity and responsiveness of the Norwegian version of the EAC for this group of patients.

Methods: 220 patients with different rheumatic diseases were included in a cross-sectional study in which data quality and internal consistency were assessed. Construct validity was assessed through comparisons with the Brief Approach/Avoidance Coping Questionnaire (BACQ) and the General Health Questionnaire (GHQ-20). Responsiveness was tested in a longitudinal pretest-posttest study of two different coping interventions, the Vitality Training Program (VTP) and a Self-Management Program (SMP).

Results: The EAC had low levels of missing data. Results from principal component analysis supported two subscales, Emotional Expression and Emotional Processing, which had high Cronbach's alphas of 0.90 and 0.92, respectively. The EAC had correlations with approach-oriented items in the BACQ in the range 0.17-0.50. The EAC Expression scale had a significant negative correlation with the GHQ-20 of -0.13. As hypothesized, participation in the VTP significantly improved EAC scores, indicating responsiveness to change.

Conclusion: The EAC is an acceptable and valid instrument for measuring emotional processing and expression in patients with rheumatic diseases. The EAC scales were responsive to change in an intervention designed to promote emotion regulation. The instrument has not yet been tested for test-retest reliability, which is recommended in future studies.

Background

Chronic rheumatic diseases often have an important impact on physical, as well as psychological and social aspects of patients' lives. Such long-term stressors that have uncontrollable elements can place great emotional demands on the individual. Research has documented a high degree of depression, anxiety and psychological distress in patients with rheumatoid arthritis (RA) and other rheumatic diseases [1-6].

There are individual differences in how patients cope with various symptoms and adjust to the burden of the disease. In early stages of the disease emotional distress is associated with levels of pain and fatigue, functional status, disease impact on daily life, life events and perceived social support [1,7]. The effect of disease-related factors on psychological distress seems to decrease [3,8] and personality characteristics and individual coping resources appear to become more important predictors over time [7,9]. Various self-management interventions have been developed to improve patients' ability to cope with the complexity of symptoms related to their rheumatic disease [10-12]. There is a growing consensus that emotion regulation, in terms of acknowledging and dealing with negative emotions associated with chronic illness, can contribute to adjustment [13,14]. However, few interventions explicitly address patients' emotional response to their disease [9,15].

The Vitality Training Program (VTP) is a Norwegian group intervention [16], which has a special focus on awareness of and reflection upon one's own emotions, thoughts and bodily experiences. It has produced a reduction in psychological distress and increased emotional well-being in a randomized, controlled trial in persons with chronic musculoskeletal pain [17] and in a one-year follow-up of a non-controlled study for patients with inflammatory rheumatic diseases [18]. The results shall be further evaluated in a randomized, controlled trial. However, following a search of the literature, no acceptable instrument to measure intervention-related change in patients' coping strategies related to emotional awareness was found.

The coping literature makes a distinction between problem-focused and emotion-focused coping strategies [19-21]. Problem-focused coping includes direct efforts to alter the demands on the person, whereas emotion-focused coping includes efforts to regulate emotions associated with stressful situations. Research based on earlier published coping scales has found that use of emotion-focused coping strategies is often associated with psychological distress and maladjustment [13,20,22]. However, there is increasing research on the adaptive nature of acknowledging, processing, and expressing one's emotions. An ability to approach one's and others' emotions is seen as crucial to healthy intra- and interpersonal functioning [13-15,23]. This view has also received empirical support through studies on emotional disclosure interventions [24-29].

Major problems have been identified in the existing conceptualization and measurement of emotion-focused coping [13,20,22]. Diverse coping methods, such as approach-oriented (e.g. *seeking social support*) and avoidance-oriented (e.g. *denial*) strategies, have been assessed with emotion-focused coping items, some of which are inversely correlated. Emotion-focused coping scales have also included items related to emotional distress and negative emotions (e.g. *angry, upset, blame myself*). Hence, these earlier measures of emotion-focused coping were confounded by aspects of psychological health. Stanton et al [22] developed a construct of emotional approach coping which does not include distress-related items. Based on this construct, the Emotional Approach Coping Scale (EAC) is comprised of two factors [22]: Emotional Processing, which includes active attempts to acknowledge, explore meanings and come to an understanding of one's emotions; and Emotional Expression, which includes active verbal and/or nonverbal attempts to communicate or symbolize one's emotional experience. The EAC has been tested in clinical samples [13], including patients with chronic myofascial pain [29]. These studies show that emotional approach coping is inversely related to psychological distress and can predict better adjustment and less pain and depression over time [13,22,29].

The aim of this study was to evaluate the Norwegian version of the EAC in patients with rheumatic diseases. More specifically, the instrument was tested for data quality, internal consistency reliability and construct validity in a cross-sectional study. Responsiveness to change was assessed using longitudinal data from a pretest-posttest study that included patients recruited from two different coping interventions, the VTP and an inpatient Self-Management Program (SMP).

Methods

Data collection

Recruitment of three different groups of patients took place in 2007 and all received self-completed questionnaires. For the cross-sectional study, 118 consecutive patients (group 1) who had a confirmed rheumatological diagnosis and who attended regular consultations at rheumatology inpatient, outpatient or day hospital clinics, were recruited. Questionnaires were given to patients by rheumatology nurses at a single data collection point. For the pretest-posttest study, 49 patients (group 2) attending four VTP groups and 103 patients (group 3) attending five diagnosis-specific SMP courses were recruited. Group 2 were given questionnaires by facilitators immediately

before the first VTP session and were mailed questionnaires after the last session. Group 3 were given the questionnaires by a nurse at the beginning of the first day of the SMP and at the end of the last day of the course. Baseline data from group 2 and 3 and all data from group 1 were used in the cross-sectional study.

Inclusion criteria were adults with confirmed rheumatological diagnosis in the consecutive sample (group 1) and confirmed rheumatological diagnosis of at least six months duration and age over 20 years in the two coping interventions (group 2 and 3). All patients received written and oral information regarding the study, and informed consent was obtained from all patients before entering the study. Group 1 patients were free to either fill out the questionnaire or not; questionnaires were sent back anonymously. This survey was regarded as a component of quality assurance and hence ethical approval was not required. The pretest-posttest study samples participated in two evaluation studies, which both were approved by the Regional Committee for Medical Ethics.

Interventions

The VTP aims at helping patients to become more aware of their internal and external resources in order to cope with their current life situation. Processing, acknowledging, and expressing one's emotions are central elements. Through participation-based teaching and counselling methods, as well as awareness and relaxation training, patients learn to accept their thoughts, feelings and bodily experiences as they are, and respond to their symptoms, other people, and situations in more adaptive ways. The VTP lasts for approximately 4 months, involving 10 sessions of process-oriented group learning for 8 to 12 patients with different rheumatic diseases. Each group is facilitated by two health professionals (nurses, physiotherapists, occupational therapists or social workers), who have completed a one-year postgraduate program in the VTP. The one-week inpatient Self-Management Program (SMP) is taught in disease specific groups for 16 patients, consisting of consultation with a rheumatologist, multidisciplinary disease specific teaching, physical exercises and sharing experiences in small groups. The aim of this intervention is to strengthen the patients' ability to manage symptoms, treatment, and physical and psychosocial life style changes inherent in living with a rheumatic disease.

Measures

The EAC comprises 16 items that form two subscales; Emotional Processing (8 items) and Emotional Expression (8 items). The items have a 4-point scale of "I don't do this at all", "I do this a little bit", "I do this a medium amount" and "I do this a lot". The mean item score is calculated for each subscale. The two subscales have satisfactory internal consistency and test-retest reliability in samples of undergraduate students [22].

The original US version of the EAC underwent a forward and backward translation [30]. Two Norwegians proficient in English independently translated the questionnaire into Norwegian. One licensed translator, and a person who was proficient in English carried out the backward translation independently. The forward and backward translations were discussed by the translators, a psychologist and the research group. Discrepancies between the various versions were resolved by consensus in order to achieve conceptual equivalence between the Norwegian and original US versions of the EAC. The consensus version of the back-translation was mailed to the original author (ALS) who confirmed semantic equivalence. In the current study, participants were instructed to complete the items with reference to how they usually respond to emotions related to their chronic rheumatic disease.

The Brief Approach/Avoidance Coping Questionnaire (BACQ) comprises 12 items designed to measure a general concept of approach-versus avoidance-oriented coping. Items have a 5-point Likert scale from "strongly disagree" to "strongly agree". The BACQ had satisfactory psychometric properties in a Norwegian population of primary care patients [31].

The General Health Questionnaire (GHQ-20) comprises 20 items and measures several aspects of psychological distress during the previous 2 weeks [32,33]. Items have a 4-point scale of "not at all", "no more than usual", "rather more than usual" and "much more than usual". The total score ranges from (0) no distress at all to (60) severe distress. The GHQ has been shown to be valid and reliable across cultures [34] and the GHQ-20 has been widely used in Norwegian studies [35,36].

Statistical analyses

Levels of missing data were assessed for the EAC items and scales. Evidence for the existence of the two EAC subscales was assessed by principal component analyses (PCA) with varimax rotation [37]. Components with eigenvalues greater than one were considered potentially important.

Internal consistency

Internal consistency was assessed by item-total correlations and Cronbach's alpha. For a scale to be sufficiently reliable for use in groups of patients, an alpha value of 0.70 is considered acceptable [38,39].

Construct validity

Construct validity was assessed by comparing the EAC scores with the BACQ and GHQ-20 with Pearson's corre-

lation coefficient [39-41]. We hypothesised that the EAC scores would be positively related to approach-oriented items in the BACQ. EAC subscales and the BACQ measure distinct aspects of coping, and hence correlations with the BACQ were not expected to be high, but of a low to moderate level (0.3 - 0.6). Because the EAC scales were designed to be unconfounded by distress-laden content [22], we expected the correlations with GHQ-20 to be negative and of a low magnitude under 0.3.

Responsiveness to change

Responsiveness refers to an instrument's ability to measure change over time [39,42,43]. This was assessed in the VTP and the SMP samples by the standardized response mean (SRM). SRMs were calculated by dividing the mean change scores by the standard deviation (SD) of the change scores. Effective processing and expression of emotions are more central elements in the VTP than in the SMP, and hence it was hypothesised that relative to SMP participants, the VTP participants would have a larger increase in the EAC scores.

All analyses were performed with SPSS, version 14.0 (SPSS Inc., Chicago, IL, USA).

Results

Data collection

A total of 220 patients were included in the cross-sectional study; 118 in group 1, 66 (64.1%) in group 2 and 36 (73.5%) in group 3 (table 1). Patients had a mean age of 50.3 (SD 12.63), 165 (75.0%) were women and following diagnoses were reported: rheumatoid arthritis (58), ankylosing spondylitis (38), psoriatic arthritis (32), fibromyalgia (31), osteoarthritis (25), connective tissue diseases (11), juvenile rheumatoid arthritis (4) and others (18). Group 1 patients attending the rheumatology clinic were more likely to be men and had significantly longer disease duration than the two others. Group 3 patients attending the VTP, were significantly younger than the two other groups. No significant differences were found for other variables assessed at baseline (table 1).

Statistical analyis

Overall, patients were able to complete the EAC questionnaire without help. There were few missing values, and these ranged from 1.9% to 5.7% for items relating to Emotional Expression and Emotional Processing, respectively. Mean item scores (SD) ranged from 2.51 (0.89) to 3.32 (0.66) (table 2).

Principal component analysis yielded two components with eigenvalues 7.25 and 2.79; a third weak component had an eigenvalue of 0.97. The first two components accounted for 62.7% of the total variance. Both components had high loadings, the majority (14/16) being over 0.6 and clearly reflecting the two hypothesized domains of Emotional Expression and Emotional Processing.

Internal consistency

Item-total correlations all exceeded 0.45. Both the EAC Expression and Processing scales met the Cronbach's alpha criterion of 0.70.

There were very little missing data at the scale level. Whilst item scores were generally skewed towards positive levels of coping, the domain scores were more normally distributed with means of 2.84 (0.63) and 2.71 (0.63) for Emotional Processing and Emotional Expression, respectively (table 2). End effects were low; 3 (1.36%); and 0 patients scored at the floor and 10 (4.55%) and 14 (6.36%) scored at the ceiling for Emotional Expression and Emotional Processing, respectively.

Construct validity

As hypothesised the EAC scales had low to moderate correlations with the approach-oriented items in the BACQ. The EAC Expression scale had significant moderate correlations with the BACQ items "I say so if I am angry or sad" and "I like to talk to a few chosen people when things get too much for me", but had only weak correlations with the other approach-oriented items. The EAC Processing scale had a significant moderate correlation with the item "I like to talk to a few chosen people when things get too much for me" and was only weakly correlated with the other approach-oriented items (table 3). There were no significant correlations between the EAC scales and the avoidance-oriented items in BACQ. The EAC Expression scale had a low, but significant, negative correlation with the GHQ-20, such that higher emotional expression was associated with lower distress, supporting the hypothesis that the EAC scales are unconfounded of distress-laden content. The correlation between the EAC Processing scale and the GHQ-20 was very low and not significant.

Responsiveness to change

Twenty-six (72%) of the included patients in group 2 completed a questionnaire after the VTP. All included group 3 patients attending the SMP completed a questionnaire after the program. As hypothesised the EAC scores increased more in the VTP sample than in the SMP sample. In the VTP sample, there were significant increases in both EAC Processing and EAC Expression. This group also showed a significant reduction in GHQ-20 scores. The SRMs were between 0.40 and 0.73. There were no significant changes in the EAC scales in the SMP sample at follow-up, but a significant reduction was found in the GHQ-20 scores (table 4).

Discussion

This study has translated the EAC to Norwegian following established guidelines for forward-backwards translation

Table 1: Baseline characteristics of patients (n = 220)

	Group 1	Group 2	Group 3
	Rheumatology	**Vitality Training**	**Self-Management**
	clinics (n = 118)	**Program (n = 36)**	**Program (n = 66)**
Age, mean (range)	49.9 (17 - 78)	45.9 (29 - 71)*	53.3 (25 - 86)
Female, n(%)	71 (60.7)**	34 (94.4)	60 (90.9)
Disease duration, mean (range)	10.0 (0 - 47)***	5.0 (1 - 45)	5.0 (0.5 - 32)
Diagnosis, n (%):			
rheumatoid arthritis	48 (41.7)	10 (27.8)	0
ankylosing spondylitis	22 (19.1)	6 (16.7)	19 (15.2)
psoriatic arthritis	20 (17.4)	5 (13.9)	7 (10.6)
fibromyalgia	2 (1.7)	8 (22.2)	21 (31.8)
connective tissue disease	5 (4.3)	0	6 (9.1)
osteoarthritis	1 (0.9)	2 (5.6)	22 (33.3)
juvenile arthritis	3 (2.6)	1 (2.8)	0
others	14 (12.2)	4 (11.1)	0
EACscales:			
Emotional Processing	2.78 (0.6)	2.96 (0.6)	2.83 (0.7)
Emotional Expression	2.68 (0.6)	2.60 (0.7)	2.76 (0.6)
BACQ	3.28 (0.4)	3.25 (0.5)	3.15 (0.4)
GHQ - 20	22.01 (9.8)	24.06 (7.8)	22.48 (9.6)

Emotional Processing: 1 = low processing, 4 = high processing
Emotional Expression: 1 = low expression, 4 = high expression
BACQ = Brief Approach/Avoidance Coping Questionnaire: 1 = low approach, 4 = high approach
GHQ - 20 = General Health Questionnaire: 0 = no distress, 60 = high distress
Values are means (SD) for continues variables and frequencies (percentages within sample) for categorical values.
Disease duration = median years since diagnosis.
* significant lower mean than the two other samples ($p = 0.027$)
** significant lower proportion than the two other samples ($p < 0.001$)
*** significant higher median than the two other samples ($p < 0.001$)

[30]. The Norwegian version of the EAC was found to be acceptable to patients with rheumatic diseases and had low levels of missing data. The results of PCA show that the two scales defined by the instrument's authors are supported empirically. The EAC scales also have good evidence for internal consistency and construct validity. As hypothesized, the EAC scales were responsive to change in an intervention designed to promote effective emotion regulation (VTP), but not in an intervention with less focus on managing emotions (SMP).

The items "I realize that my feelings are valid and important" and "I acknowledge my emotions" had the lowest item-total correlations. The content of these two items may be interpreted as reflecting the value of one's emotions. They loaded satisfactorily on the emotional process-

Table 2: Descriptive statistics, component loadings and internal consistency of the EAC (n = 220)

Scale/item	Missing (%)	Mean (SD)	Frequency %				Component loading[a]	Cronbach's α/item-total correlation
			Not at all	A little	Moderately	A lot		
Emotional processing[b]		2.84 (0.63)	-	-	-	-	-	0.90
Take time to figure out	1 (0.5)	2.79 (0.77)	8 (3.6)	73 (33.2)	100 (45.5)	38 (17.3)	0.71	0.88
Delve into feelings	0	2.62 (0.83)	14 (6.4)	92 (41.8)	79 (35.9)	35 (15.9)	0.81	0.88
Validity/ importance	3 (1.4)	3.28 (0.69)	6 (2.7)	17 (7.7)	105 (47.7)	89 (40.5)	0.58	0.90
Acknowledge emotions	5 (2.4)	3.32 (0.66)	0	25 (11.4)	96 (43.6)	94 (42.7)	0.46	0.90
Work on understanding	0	2.88 (0.84)	11 (5.0)	64 (29.1)	87 (39.5)	58 (26.4)	0.84	0.88
Explore emotions	2 (0.9)	2.51 (0.89)	30 (13.6)	85 (38.6)	72 (32.7)	31 (14.1)	0.80	0.88
Find way to understand	1 (0.5)	2.69 (0.84)	15 (6.8)	82 (37.3)	84 (38.2)	38 (17.3)	0.80	0.88
Look closely at reasons	0	2.72 (0.91)	20 (9.1)	72 (32.7)	79 (35.9)	49 (22.3)	0.85	0.88
Emotional expression[b]		2.71 (0.63)	-	-	-	-	-	0.92
Take time to express	0	2.62 (0.76)	10 (4.5)	89 (40.5)	94 (42.7)	27 (12.3)	0.62	0.91
Let feelings come out	0	2.57 (0.84)	21 (9.5)	84 (38.2)	87 (39.5)	28 (12.7)	0.79	0.91
Allow myself to express	0	2.75 (0.81)	14 (6.4)	62 (28.2)	110 (50.0)	34 (15.5)	0.85	0.90
Feel free to express	0	2.92 (0.84)	15 (6.8)	45 (20.5)	109 (49.5)	51 (23.2)	0.75	0.91
Express feelings I have	1 (0.5)	2.77 (0.74)	8 (3.6)	66 (30.0)	113 (51.4)	32 (14.5)	0.86	0.90
Find way to express	2 (0.9)	2.80 (0.72)	8 (3.6)	58 (26.4)	122 (55.5)	30 (13.6)	0.62	0.92
Let feelings out	0	2.65 (0.82)	16 (7.3)	85 (38.6)	88 (40.0)	31 (14.1)	0.87	0.90
Get feelings out	1 (0.5)	2.67 (0.77)	13 (5.9)	80 (36.4)	100 (45.5)	26 (11.8)	0.82	0.90

[a] Emotional expression and emotional processing had eigenvalues of 7.25 and 2.79 respectively
[b] The two EAC scales are scored from 1-4 where 4 reflects the most frequent use of EAC

ing factor, but might as well have contributed to a third factor. Looking at the skewed distributions of these two items, we also found a ceiling effect, which may reflect a high threshold for saying that one's emotions are not valid and acknowledged. There were some missing values for these items, and hence they may have been more difficult to interpret for some patients.

Both EAC scales have high internal consistency which follow previous findings [22,29]. The high Cronbach's alpha for the EAC Expression scale (0.92) may indicate that some of the items in this scale are unnecessary. An earlier version of the EAC comprised two four-item scales [22] which were expanded to eight-item scales. The longer version was found to have slightly higher reliability, which was the reason for choosing the longer-form version for this cross-cultural adaptation. If the EAC is to be used with groups of patients, then it might be argued that the four-item scales will suffice. However, if the instrument is to be used in clinical practice for assessing individual patients then the longer-form is recommended since it meets the minimum criterion of a Cronbach's alpha of 0.90 [44].

Both EAC scales were related to the approach-oriented items in the BACQ and uncorrelated with the avoidance-oriented items, supporting construct validity. As expected, the correlations were strongest between EAC Expression and the expressive BACQ items. The inverse correlation between EAC Expression and the GHQ-20 scores supports the hypothesis that EAC Expression is related to positive adjustment, rather than dysfunction. From the negative correlation it may be concluded that the concept of coping through expressing one's emotions is distinct from psychological distress. Taken together, these findings correspond with previous studies that concluded that emotional approach coping is conceptually different from

Table 3: Correlation between the EAC scores, BACQ and GHQ-20 (n = 220)

	EAC processing	EAC expression
EAC processing	-	0.48**
EAC expression	0.48**	-
BACQ total	0.29**	0.40**
1 I say so if I am angry or sad	0.18*	0.50**
2 I like to talk to a few chosen people when things get too much for me	0.39**	0.44**
4 I make an active effort to find a solution to my problems	0.26**	0.17*
8 I think something positive could come out of my complaints/problems	0.24**	0.22**
9 I firmly will believe that my problems will decrease	0.08	0.13*
GHQ-20	- 0.01	-0.21*

* $p < 0.05$, ** $p < 0.01$

Table 4: Responsiveness of the EAC, BACQ and GHQ-20 in the VTP§ (n = 26) and the SMP§ (n = 66)

	Baseline	Follow-up	Change scores	SRM
	mean (SD)	mean (SD)	mean (SD)	
EAC processing				
VTP (4 months)	3.12 (0.60)	3.39 (0.64)	- 0.27 (0.58)*	0.47
SMP (1 week)	2.83 (0.66)	2.93 (0.66)	- 0.10 (0.52)	0.19
EAC expression				
VTP (4 months)	2.69 (0.64)	3.06 (0.56)	- 0.37 (0.53)**	0.70
SMP (1 week)	2.76 (0.63)	2.82 (0.57)	- 0.06 (0.45)	0.13
BACQ total				
VTP (4 months)	3.41 (0.42)	3.55 (0.46)	- 0.14 (0.35)	0.40
SMP (1 week)	3.14 (0.44)	3.22 (0.45)	- 0.08 (0.36)	0.22
GHQ-20				
VTP (4 months)	24.88 (9.40)	16.23 (9.33)	8.65 (11.80)**	0.73
SMP (1 week)	22.94 (9.96)	17.55 (8.89)	5.39 (7.15)**	0.75

§ VTP = the Vitality Training Program, SMP = the Self Mangement Program
* $P < 0.05$, ** $P < 0.001$, Values refer to statistical differences in mean scores between T1 and T2
SD = Standard deviation
SRM = Standardized Response Mean

passive, avoidance-oriented coping and from other emotion-focused coping strategies related to distress [22,29].

The findings supported the hypothesis that patients with rheumatic diseases participating in the VTP would increase their EAC, whereas participants in the SMP would not. The two interventions are different in both length and content. In the SMP, active problem-focused coping strategies are emphasized. Even though emotional distress is a topic in the program, the participants are not invited to explore and understand their own emotional coping strategies to the same degree as in the VTP. Therefore it was not expected that this one-week program would change emotion-focused coping strategies. In contrast, the VTP is a four-month process-oriented program with a special focus on emotions, and hence a change in emotion-focused coping strategies was expected. Both EAC scale scores improved significantly after the VTP. The smaller, significant change in EAC Processing may be due to the relatively high score at baseline, making it difficult to detect change. There were also a small number of patients in the VTP sample so the results should be interpreted with some caution. Few studies have examined EAC as an outcome or moderator of effects of emotion regulation interventions [22,28,45-48]. Findings in this study indicate that the EAC may be used as an outcome measure in interventions for patients with rheumatic diseases where emotional approach coping is targeted.

A limitation in this study is that the EAC was compared with only two other measures to assess construct validity and comparisons with other scales measuring approach/avoidance-oriented coping and active/passive coping are recommended. Another limitation is that the instrument has not yet been tested for test-retest reliability, which is recommended in future studies. Test-retest data would also have allowed the calculation of the responsiveness statistic, which takes account of score variation in patients who are stable [49]. Receiver operating characteristic (ROC) curves [50] is a further method of assessing responsiveness but the absence of a criterion relating to whether patients had an important improvement in coping limited the scope for ROC analysis in this study. The identification of patients that have had an important change in their coping based on clinical or patient judgments can also facilitate the interpretability of EAC subscale scores [38]. The short follow-up period in the pretest-posttest study is a further study limitation, which limits the conclusions relating to responsiveness.

Conclusion

The results of this study show that the EAC has evidence for data quality, internal consistency and validity, but has yet to be assessed for test-retest reliability, which is recommended in future studies. The study has also shown that participation in the VTP improves emotion-focused coping strategies as measured by the EAC in patients with various rheumatic diseases, showing that the EAC scales are responsive to change. Further studies based on larger samples with a longer follow-up period that include other important psychological and health-related outcome measures are recommended.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

HAZ, KBH and AF conceived the study; ALS developed the original instrument; HAZ coordinated the data collection; PM, AG, KBH and HAZ performed the statistical analyses; HAZ, AG, KBH, AF and ALS drafted the manuscript. All authors read and approved the final manuscript.

Acknowledgements

The study was funded by the National Resource Center for Rehabilitation in Rheumatology, Diakonhjemmet Hospital, Oslo. The authors would like to thank Bente Hamnes for participating in the translation of the EAC and for allowing us to use data from the SMP-sample. We also thank Solveig Berre, Liv R. Eriksson, Elfrid Flataker, Kristine Hagelund, Hege Koksvik, Birgit S. Næss, Aud Rønningen and Hanne K. Vestaby who aided with data collection.

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Pre-publication history

The pre-publication history for this paper can be accessed here:

http://www.biomedcentral.com/1471-2474/10/107/prepub

IV

Appendix

The Emotional Approach Coping Scale

SPØRSMÅL OM FØLELSER

Setningene nedenfor handler om hvordan du forholder deg til følelsene dine. Ulike situasjoner kan fremkalle ulike følelser med ulik styrke. Her er det ikke noe som er "riktig" eller "galt". Velg det svaret som er så sant som mulig FOR DEG; ikke tenk på hva andre ville si eller gjøre. Les hver setning nøye og kryss av for hva du vanligvis gjør.

		Ikke dette i det hele tatt	I liten grad	I middels grad	I stor grad
1.	Jeg tar meg tid til å finne ut hva jeg virkelig føler	☐	☐	☐	☐
2.	Jeg går inn i følelsene mine for å forstå dem ordentlig	☐	☐	☐	☐
3.	Jeg er klar over at følelsene mine er sanne og viktige	☐	☐	☐	☐
4.	Jeg vedstår meg følelsene mine	☐	☐	☐	☐
5.	Jeg arbeider med å forstå følelsene mine	☐	☐	☐	☐
6.	Jeg utforsker følelsene mine	☐	☐	☐	☐
7.	Jeg finner måter å forstå følelsene mine bedre på	☐	☐	☐	☐
8.	Jeg ser nøye på årsakene til følelsene mine	☐	☐	☐	☐
9.	Jeg tar meg tid til å uttrykke følelsene mine	☐	☐	☐	☐
10.	Jeg lar følelsene mine få komme fritt fram	☐	☐	☐	☐
11.	Jeg tillater meg selv å uttrykke følelsene mine	☐	☐	☐	☐
12.	Jeg føler meg fri til å uttrykke følelsene mine	☐	☐	☐	☐
13.	Jeg uttrykker de følelsene jeg har	☐	☐	☐	☐
14.	Jeg finner en måte å uttrykke følelsene mine på	☐	☐	☐	☐
15.	Jeg slipper følelsene mine ut	☐	☐	☐	☐
16	Jeg får følelsene mine fram	☐	☐	☐	☐

Emotinal Approach Coping Scale (Stanton et al 2000)