

# THOUGHT FIELD THERAPY FOR PATIENTS WITH ANXIETY DISORDERS.

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**UiO : Universitetet i Oslo**



EXTRA  
STIFTELSEN



Rådet for psykisk helse

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## **Preface**

From 1990 I worked as a psychiatrist in an open twelve-bed ward which was closed during the weekends. Often one half of the patients had post-traumatic stress disorder (PTSD) as their main diagnosis, most of them due to long-lasting sexual and/or violent abuse during several years of their childhood. I found it difficult to give them proper treatment, and I was searching for effective therapies that were gentler for the patients. I learned a lot from a seminar with Edna Foa in 1994, and practiced exposure therapy according to her model. It proved efficient, but was hard for patients to go through.

During the following years I learned and applied several other methods for treating PTSD, such as Traumatic incident reduction (TIR), Mervin Smucker's Imagery Rescripting and Reprocessing Therapy (IRRT) and Eye movement desensitization and reprocessing (EMDR).

Unfortunately I did not achieve very good results with the EMDR, for whatever reason, and so I was curious when informed about a promising and for me totally new therapy, Roger Callahan's Thought field therapy (TFT) in 2000. In seminars I observed some great results after one session, and the patients who were effectively treated told that they had a totally different understanding of their symptoms after only 20 to 30 minutes of treatment. Post-treatment they reported that they could think and speak of terrible incidents without experiencing their former unpleasant emotional reactions.

I applied TFT for some patients and had similar experiences of effectiveness with some, but not all. As research was sparse on this therapy, I felt an obligation to examine if it would prove effective in larger and methodologically sounder studies than case reports. Being a novice in scientific research, my first study had many limitations, which are discussed in Paper 1 in this thesis. I therefore decided to do a randomized controlled study on patients with severe symptoms of one anxiety disorder, agoraphobia, comparing TFT to the recommended psychotherapy (CBT/CT) for this disorder, Paper 2. My reasons for choosing agoraphobia as the study diagnosis were that in the first study I found many patients having this condition, with massive symptoms and suffering, and I had experienced the diagnosis of agoraphobia to be fairly easy to delimit from other psychiatric disorders.

My experience is that Cognitive therapy (CT) and Cognitive behavioral therapy (CBT) are used interchangeably. I have been used to calling it CBT, but

the comparative treatment in Study 2 is called CT (Hawton, Salkovskis, Kirk, & Clark, 1989). In this thesis I will use CBT in line with a statement by Judith Beck (J. S. Beck, 2011) page 2 where she asserts that the terms CT and CBT are used synonymously. However, when I specifically refer to the comparative therapy in Study 2, as being CT, I call it CT.

## **Acknowledgements**

Many people have helped me with the scientific and clinical work leading to this thesis through the years from 2001 till now, and I am very thankful to all of them. First and foremost I will thank my supervisors, Asle Hoffart, Toril Dammen and Egil W. Martinsen. You have given me enormous help and support in all parts of this work. Special thanks to you Asle, who have helped me all the way since 2004, and have had to tolerate time and again my lack of knowledge in all but clinical work. I will give special thanks also to Toril and Egil for educational efforts and abundant support in how to write a thesis, to Toril in addition for co-authoring the three papers. Without Asle, Toril and Egil there would have been no thesis! Here I will also thank Alv A. Dahl, who supervised my planning of the first study on which this thesis is based.

I will thank Eva Cecilie Orvin for doing some of the diagnostic interviews in the first study, and Mats Uldal who spent two busy weeks offering TFT to 49 patients, without a penny in return. Sadly Mats died in December 2016.

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I wish to thank Are Pripp and Torbjørn Moum for statistical help and advice, Torbjørn also for helping with my English grammar and spelling; Joe Himle, Anne H. Udal and Tor Erik Nysæter for helping me writing the papers, Stein Lund Halvorsen for evaluating videos from the TFT treatment in Study 2 and Ole Jørgen Gundersen for saving my manuscripts from the terror of the (to me) unknown world of Word, more than once. I will also thank my sister-in-law Marit Nenseter for good advice on writing scientific papers, and Linda Reme Sagedal for helping me with writing in English.

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also thank the department leaders for letting me carry on this research in addition to my other tasks: Olaf Bakke, Oddvar Sæther, Helge Skard Dokka, Henning Garsjø, Anne-Brit Dræge and Joyce Pigao. And I will most definitely thank my colleagues in the Intensive group care unit and especially psychologist Marit Olsen, for taking on heavy clinical burdens, making it possible for me to conduct the studies and write the papers.

I wish to thank all the patients who participated in the two studies, for being willing to be randomized rather than deciding the therapy for themselves, and for showing up for therapy sessions and follow-up. Few studies report such a low number of patient drop outs both during treatment and at follow-up.

My deepest thank goes to you Hilde, my wife and closest friend since December 26<sup>th</sup> 1976. I love you, and I appreciate our friendship and all we do together. Dear sons, Theis Håvard and Kolbjørn. You are the jewels of my life. I care for you from the deepest of my heart, for you and for your dearest, Ane and Hilde.

## **Objective**

### Summary

Thought Field Therapy (TFT) is in widespread use, but its efficacy has been studied only to a small extent. Therefore, there is a need for randomized controlled studies that examine whether TFT yields favorable results for patients with psychiatric illnesses. Since TFT is often applied for anxiety disorders, such disorders were chosen as the object for this thesis. Besides, anxiety disorders are common and make many people suffer, and unfortunately there are not enough therapists available.

The specific research questions were: Does TFT show effects for patients with anxiety disorders (Paper 1)? For patients with agoraphobia, what is the effect of TFT compared to that of cognitive therapy (CT) and a wait-list condition (Paper 2)? Can we identify predictors of treatment outcome in the sample as a whole, and can we find moderators of the treatment outcome of CT relative to that of TFT (Paper 3)?

### Design:

This thesis consists of two randomized, controlled trials (RCTs). The first trial compared TFT to wait-list for patients with one or more anxiety disorders, and the second trial compared TFT to both wait-list and Cognitive therapy (CT) for agoraphobia. Both trials included twelve months follow up assessments.

### Samples:

Trial one: Forty-five patients with at least one current anxiety disorder. Trial two: Seventy-two patients with agoraphobia as their primary psychiatric disorder.

### Assessments:

Diagnoses were assessed by diagnostic interviews: Mini International Neuropsychiatric Interview (MINI, MINI PLUS), Iowa Personality Disorder Screen (IOWA), Structured Clinical Interview for DSM Personality Disorders (SCID II), and Anxiety Disorders Interview Schedule for DSM-IV: Life Time Version: Client Interview Schedule (ADIS). Levels of symptoms were assessed by the following questionnaires: Symptom Checklist 90-Revised (SCL 90-R), Hospital Anxiety and Depression Scale (HAD), Sheehan Disability Scale (SDS), the anxiety and avoidance scales and scores on inference and distress from the ADIS, Mobility Inventory Alone (MIAAL), Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), Agoraphobic Cognitions Questionnaires (ACQ), Body

Sensations Questionnaire (BSQ). Demographic data were collected by interviews.

Results:

The main findings of this thesis are:

For patients with anxiety disorders TFT significantly reduced anxiety symptoms compared to wait-list participants, and the beneficial effects of TFT remained at three- and 12-month follow-up for the sample as a whole.

TFT showed beneficial effects for agoraphobia both comparing pre-post treatment and pretreatment to 12-month follow-up. We did not find any significantly different results of TFT compared to CT, although there was a trend towards better outcomes for CT on all measures except avoidance and anxiety comparing pretreatment to 12-month follow-up.

We identified being cohabitant/married and current depressive disorder as positive and negative predictors respectively and as moderators of the outcome of treatment modalities for agoraphobia.

Conclusions:

TFT appears to be an effective treatment for anxiety disorders, but there is a need both for studies on the effectiveness of TFT for other anxiety disorders as well as more studies of TFT for agoraphobia, preferably compared to CBT. As CBT shows good results for anxiety disorders, the comparative studies should be powered to be able to demonstrate non-inferiority for TFT vs. CBT.

If both therapies are available for a patient in need of treatment for agoraphobia one should always choose CBT over TFT, especially if the patient has a concurrent depressive disorder.

## List of papers

### Paper 1

Irgens A, Dammen T, Nysæter TE, Hoffart A. Thought Field Therapy (TFT) as a treatment for anxiety symptoms: A randomized controlled trial. Explore: The Journal of Science and Healing 2012; 8:331-8.

### Paper 2

Irgens A, Hoffart A, Nysæter TE, Haaland VØ, Borge FM, Pripp AH, Martinsen EW, Dammen T. Thought Field Therapy compared to Cognitive Therapy and wait-list for agoraphobia: A randomized, controlled study with a 12-month follow-up. Frontiers in Psychology 2017; 8: 1027.

### Paper 3

Irgens A, Hoffart A, Moum T, Udal AH, Nysæter TE, Pripp AH, Dammen T. Prediction and Moderation of Outcome in Cognitive-Behavioral and Thought-Field Therapy for Agoraphobia. Submitted.

## **Abbreviations**

ACQ: Agoraphobic cognitions questionnaire

ADIS: Anxiety disorders interview schedule

ANCOVA: Analysis of covariance

ANOVA: Analysis of variance

BAI: Beck anxiety inventory

BDI: Beck depression inventory

BSQ: Body sensations questionnaire

CAM: Complementary and alternative medicine

CBT: Cognitive behavior therapy

CI: Confidence interval

CT: Cognitive therapy

CTS: Cognitive therapy scale

DB: Diaphragmatic breathing

DSM-IV: Diagnostical and statistical manual of mental disorders version four

EFT: Emotional freedom techniques

EMDR: Eye movement desensitization and reprocessing

EXTRA: Norwegian ExtraFoundation for Health and Rehabilitation

GSI: The global severity index from SCL-90-R

HAD: Hospital anxiety and depression scale

GAD: Generalized anxiety disorder

ICD-10: International statistical classification of diseases and health related problems, 10<sup>th</sup> revision

IOWA: Iowa personality disorder screen

IRRT: Imagery Rescripting and Reprocessing Therapy

ITT: Intention to treat

LOCF: Last observation carried forward

MI: Mobility inventory

MIAAL: Mobility inventory "Alone" subscale

MINI: Mini-international neuropsychiatric interview

MINI PLUS: Mini plus international neuropsychiatric interview

OCD: Obsessive compulsive disorder

OLS: Ordinary least squares

PCL-C : Posttraumatic checklist-civil version

PD: Personality disorder

PFPP: Panic-focused psychodynamic psychotherapy  
PTSD: Post-traumatic stress disorder  
RCT: Randomized controlled trial  
REK: Regional committee for medical and health research ethics  
SCID II: Structured clinical interview for DSM personality disorders  
SCL-90-R: Symptom checklist 90-revised  
SD: Standard deviation  
SDS: Sheehan disability scale  
SPSS: Statistical package for the social sciences  
SSRI: Selective serotonin reuptake inhibitors  
SUDs: Subjective units of discomfort  
TFT: Thought field therapy  
TIR: Traumatic incident reduction  
Y-BOCS: Yale-Brown obsessive-compulsive scale

## 1. Background

### 1.1 Anxiety disorders

Anxiety disorders are common, with a 12 month prevalence of 18.1% (Kessler, Chiu, Demler, & Walters, 2005), are often associated with other psychiatric morbidity (Martín-Merino, Ruigómez, Wallander, Johansson, & García-Rodríguez, 2009), and are disabling and often untreated in primary care (Kroenke, Spitzer, Williams, Monahan, & Löwe, 2007; Lecrubier, 2007; Weisberg, Dyck, Culpepper, & Keller, 2007). An epidemiological study from Norway found a lifetime prevalence of 6.1% for agoraphobia (Kringlen, Torgersen, & Cramer, 2001)

Martin-Merino et al reported that having an anxiety disorder was associated with serious unhealthy behaviour such as heavy alcohol use, smoking and addiction as well as sleep problems and high levels of stress, and therefore represents a serious burden of suffering and malfunction (Martín-Merino et al., 2009). Under-recognition and under-treatment of anxiety and mood disorders have been reported as a problem (Lecrubier, 2007).

In addition to the suffering caused by anxiety disorders for patients and their relatives, these disorders represent a risk of early retirement (Wedegaertner et al., 2013). Schneider et al found that anxiety may predict longer duration on sick leave, and anxiety may have been underestimated as a risk factor for an elevated number of sick leave days (Schneider et al., 2017). A Norwegian cohort study found that anxiety and depression were robust predictors of disability pension, and stated that the cost of mental disorders in terms of disability pension may have been considerably underestimated (Mykletun et al., 2006). Statistics from the Norwegian Labor and Welfare Service (NAV) showed that at the end of 2014 the percentage of persons on disability pension was 14.4 for conditions listed in WHO's International Classification of Diseases version 10 (ICD-10) Chapter 4, which describes F40-F48 Neurotic, stress-related and somatoform disorders among which anxiety disorders are listed (NAV, 2017).

The diagnosis of agoraphobia

In this study we apply the term agoraphobia as defined by the Diagnostical and statistical manual of mental disorders version four (DSM-IV), as a psychiatric diagnosis in which the patient A. Is afraid of being in situations or places in

which escape or receiving help may be difficult if the patient should experience an anxiety attack, B. Avoids such situations or needs support to not avoid them, or endure these situations with much fear and other forms of distress, and C. The anxiety and/or avoidance is not better accounted for by another mental or somatic disorder (American Psychiatric Association, 1994). Typically the fear of panic starts in one or a few situations, and then expands to more situations of daily life. We decided to study agoraphobia as a separate disorder as argued by Wittchen et al (Wittchen, Gloster, Beesdo-Baum, Fava, & Craske, 2010), although there is considerable comorbidity between agoraphobia and panic disorder (Kessler et al., 2005), and thus many of our references describe and analyze panic disorder as well as agoraphobia.

#### Agoraphobia - consequences

Panic disorder and agoraphobia have serious consequences for individuals and for society in general. The Epidemiologic Catchment Area study showed similar or greater negative impact on items tapping quality of life for those having a lifetime diagnosis of panic disorder than for those with major depression (Markowitz, Weissman, Ouellette, Lish, & Klerman, 1989). In a study from 2002 on patients with panic disorder, approximately two-thirds reported at least one pain symptom (Schmidt, Santiago, Trakowski, & Kendren, 2002).

The annual economic costs of panic disorder were estimated by Batelaan et al to be higher than the other mental disorders they studied (Batelaan et al., 2007). In addition they found that the costs were higher when agoraphobia was present. A more recent study found that, adjusted for comorbidity, panic disorder ranked as number five among the health conditions associated with the highest number of days absent from work (de Graaf, Tuithof, Van Dorsselaer, & Ten Have, 2012). This study comprised both somatic and psychiatric disorders, and reported that in terms of reduced qualitative work functioning, agoraphobia ranked as number one.

#### Guidelines for treating agoraphobia

We have not found recently published guidelines for the treatment of agoraphobia as a separate clinical condition, because its treatment is included in guidelines for panic disorders with or without agoraphobia. The internet guideline source UpToDate recommends CBT as the preferred psychotherapy



because it is most extensively supported by clinical trials (Craske, 2017). This guideline states that there is no robust evidence for choosing either antidepressant medication or CBT for panic disorder, and says that the choice between antidepressant medication and CBT can be made from availability and patients' preference (Roy-Byrne, 2017). Corresponding conclusions can be found in Canadian guidelines for treatment of anxiety disorders (Katzman et al., 2014) as well as in German guidelines (Bandelow, Lichte, Rudolf, Wiltink, & Beutel, 2014), and in the English NICE guidelines for the psychological treatment of anxiety disorders (Clark, 2011). Norwegian guidelines recommend exposure therapy as the most effective and best documented treatment for agoraphobia (Helsetilsynet, 1999).

Much has been done, especially in England to increase the availability of CBT therapists (Clark, 2011), but world-wide there is a lack of therapists with competence to deliver well-documented effective therapy (Collins et al., 2011). Therefore, there is a need to develop and test therapies that can be learned and practiced with possibly less demand on education and competency achievement than that required for CBT. Hopefully, if proven effective, such treatments would increase the availability of effective treatment and thus relieve the suffering of these patients.

## **1.2 Thought field therapy (TFT)**

In his book "Tapping the healer within" (Callahan & Trubo, 2001) the American psychologist Roger Callahan described what TFT is and how he created it. He had his clinical background in CBT and hypnotherapy, and wrote that he searched for new and faster approaches for healing. Most known is his story from 1980 about his patient Mary, whom he experimented to help by applying his knowledge from the ancient Chinese medicine of meridians. This experiment was a success, and based on this case study he was inspired to test the tapping on meridian points while asking questions to help the patients keeping their fears or overwhelming memories in mind while tapping. In this way he created algorithms for sequences of acupoints to tap for different kinds of fears or other symptoms.

When applying TFT, the patient is asked to keep in mind a situation in which the troubling feeling is activated, while at the same time instructed to tap gently on specific points on the face, hands and body. The algorithms are repeated until the subjective units of discomfort (SUDs) (Wolpe, 1990) are

down to level of 0-2. The Emotional freedom techniques (EFT) which represent an extension of TFT and were developed in the late 1990s , prescribe a fixed sequence of the same acupuncture points as those used in TFT, with an additional positive self-instruction for the patient to repeat (Craig, 2011).

### 1.3 Previous studies on TFT and EFT

To collect all relevant scientific literature before study start, we performed a search in the following data bases: AMED, Psych Info, MEDLINE, Embase, Ovid nursing, Cinahl, PubMed, SweMed+, Norart and ERIC. For details of the search strategy, please see appendix 1.

A repeated literature search was conducted in 2015 and resulted in 20 relevant clinical studies mainly on anxiety and trauma related disorders. Only five of these were carried out before our second study started in 2007.

Table 1 Clinical studies on TFT/EFT before 2007.

Study	Condition, N= number of patients included	Rando-mization	Treatment, number of sessions	Primary outcome measure	Blinded assessment	Follow up	Diagnostics
Carbonell 1997	Acrophobia (fear of heights), N=49	Yes	TFT vs sham tapping points, both one session	SUDs while exposed to height	Yes	Only pre-post	Cohen acrophobia questionnaire
Andrade & Feinstein, 2003	Anxiety, N=5000	Yes	TFT mean 3 sessions vs CBT + medication mean 15 sessions	Telephone interview scoring remission yes/no	Yes	1, 3, 6 and 12 months	Not described.
Wells et al 2003	Phobia for small animals, N=35	Yes	EFT vs diaphragmatic breathing, both one session	Behavioral approach task	Yes	6 months	Interview based on DSM-IV for specific phobia
Johnson et al 2001	PTSD symptoms, N=105	No	TFT, one session	Self-report of "bad moments"	No	1-9 months	None
Folkes, 2002	PTSD, N=29	No	TFT, one session	Post-traumatic checklist	No	30 days	Post-traumatic checklist

One of the earliest and by far the largest study of TFT is Andrade and Feinstein's report on a large multicenter study from South America, in which approximately 5 000 patients with an anxiety disorder were randomly assigned to treatment with TFT or CBT plus medication (Andrade & Feinstein, 2004). In spite of randomization and blinded assessments, the study was not planned for scientific publication due to contamination by factors such as informal record keeping and variables that were not rigorously controlled (Feinstein, 2008). The results were characterized by the authors as "amazing"; 90 % of the patients in the TFT group were rated as improved vs. 63 % in the comparison group.

Joyce Carbonell studied TFT for 49 patients with acrophobia (Carbonell, 1997). The patients were randomized to either standard TFT or a treatment condition applying other tapping points than those prescribed by TFT (sham treatment (Kaptchuk et al., 2006)). She found significantly more improvement in the TFT group than in the placebo group. This study is of interest since it is one of the very few testing the prescribed TFT tapping points compared to sham treatment tapping points. The results indicate that symptom improvement is linked to the tapping of specific tapping points rather than the tapping procedure per se. However, a serious limitation of this study is that it has not been published in an international journal with peer review, leaving uncertainty about the quality of the study.

Wells et al conducted a study of 35 participants with specific phobias of small animals (spider, mouse, rat or cockroach), randomized to treatment with EFT (N=18) or diaphragmatic breathing (N=17) (Wells, Polglase, Andrews, Carrington, & Baker, 2003). The results yielded large effect sizes post-treatment, and a significantly larger effect of EFT than that of the diaphragmatic breathing. At the 6-month follow-up there were still significant effect sizes for both therapies, but with the exception of one parameter (how near the animal the patient would go), there were no longer significant differences between the two therapies.

Johnson et al described an open study from five treatment expeditions to Kosovo after the civil war there. They reported that 103 of 105 patients showed a significant reduction of PTSD symptoms, and that most became free from PTSD symptoms after TFT treatment. Of these 105 patients, 81 patients were followed 1-9 months (median and mean both 5 months) after treatment and none of them had a relapse of symptoms. The results were described as

excellent and were published in a non-peer reviewed edition of the Journal of Clinical Psychology (Johnson, Shala, Sejdijaj, Odell, & Dabishevci, 2001). It was criticized for severe methodological limitations, such as lack of diagnostic assessments (Rosner, 2001).

A single session of TFT with 60-90 minutes duration was applied in an open study with 29 clients suffering from PTSD (Folkes, 2002). Scores on the Posttraumatic Checklist-Civil version (PCL-C) (Ruggiero, Del Ben, Scotti, & Rabalais, 2003) were obtained before and thirty days after treatment, 79 % of the participants reported significant improvements in the frequency and intensity of their traumatic stress symptoms. The authors concluded that TFT reduced the PTSD symptoms in a shorter period of time than traditional therapies, and with little discomfort for the patients. It is a limitation that the study had no comparison group.

Overall there were few studies on the effectiveness of TFT and previous studies had severe limitations (e.g. lack of diagnostic assessments, comparison groups, blinded assessments and well-defined primary outcome measures). Hence there was a need for further studies on the effectiveness for TFT for anxiety disorders using a sound methodology.

#### **1.4 Studies on predictors and moderators of outcome in treatment of agoraphobia**

Agoraphobia may be a long-lasting condition with serious consequences for patients suffering from it (Markowitz et al., 1989), and many patients experience relapse after remission (Yonkers, Bruce, Dyck, & Keller, 2003). It is therefore of clinical importance to know which factors predicting a better or worse outcome from treatment. In order to decide which type of treatment to choose or avoid for a certain patient, it would further be helpful to know if there are variables or factors that moderate the effect of a type of treatment for a specific condition, relative to that of another treatment mode.

Searching through all Ovid databases and Google Scholar, we found no studies describing predictors for therapeutic effects of TFT, regardless of diagnosis.

Three studies have identified moderators of treatment outcomes of CBT relative to other types of treatment for panic disorder with or without agoraphobia. In a study (N=41) comparing CBT to Capnometry-assisted respiratory training (CART), which is a therapy for changing maladaptory respiration, Meuret et al identified three moderators of improvement: Higher

symptom severity and greater lack of perceived control at baseline predicted better outcome for CBT than for CART, while a high baseline level of symptom appraisal predicted better outcome for CART than for CBT (Meuret, Hofmann, & Rosenfield, 2010). From a sample of 49 patients with late life panic disorder with agoraphobia, Hendricks et al concluded that higher age at onset and shorter illness duration predicted better outcome for CBT but not for paroxetine, while paroxetine may be preferred for patients with onset of symptoms before the age of 60 years (Hendriks, Keijsers, Kampman, Hoogduin, & Oude Voshaar, 2012). In a sample of 161 panic patients randomized to CBT or panic-focused psychodynamic psychotherapy (PFPP) Chambless et al found two moderators, as both low expectancy of improvement and age of onset of panic disorder below 27.5 years predicted better treatment outcome for CBT than for PFPP. Further, they found that age of onset higher than 27.5 years predicted greater positive change for patients in both treatment conditions (Chambless et al., 2017). A systematic review specifically aimed at finding moderators of treatment outcome for adults across anxiety disorders did not find moderators for panic disorders with or without agoraphobia other than those mentioned above (Schneider, Arch, & Wolitzky-Taylor, 2015).

Because there were few studies on the clinical effects of TFT in 2002 we conducted a study on TFT for anxiety disorders. Since there still were few studies of TFT for anxiety disorders in 2006, and a need for studies on TFT applying sound methodology, we conducted a study on TFT compared to CT and wait-list for agoraphobia. We also conducted a study of predictors and moderators of the outcome of TFT and CT as there is a lack of such studies.

### **1.5 Aims**

The aim of our first study was to examine the effects of TFT as a treatment for patients with a variety of anxiety disorders (paper 1), while the aim of our second study was to compare TFT to CT for patients with agoraphobia using a randomized controlled design (paper 2). In addition, our second study aimed to examine predictors of differential outcomes of TFT and CT, and to test if one or more of the predictors act as moderators of the therapeutic effect of one therapy relative to the other. In particular we wanted to test whether we could replicate findings from other studies regarding factors that putatively moderate the effect of CBT relative to that of other therapies for agoraphobia (paper 3).

## **1.6 Research questions**

This thesis addresses the following research questions:

1. What is the effect of TFT compared to a wait-list condition for patients with anxiety disorders at post-treatment, and do the changes remain stable at three and 12-month follow-up?
2. What is the effect of TFT compared to CT and to a wait-list condition in the treatment of agoraphobia at post-treatment/wait-list, and TFT compared to CT at 12-month follow-up?
3. What are the predictors of treatment outcome in terms of agoraphobic avoidance at post-treatment and 12-month follow-up for the sample as a whole?
4. What are the moderators of treatment outcome in terms of agoraphobic avoidance for CT relative to TFT?

## **2 Methods**

### **2.1 Design**

This thesis is based on two RCTs. The first compared TFT (n=23) to wait-list (n=22) for patients with different kinds of anxiety disorders. Those on the wait-list condition received TFT after a 2 ½ months waiting period and all 45 patients were followed up three and 12 months post-treatment. Assessments were performed pre-post treatment/waiting period and at the two follow ups (three and 12 months).

The second RCT compared TFT (n=24) to both CT (n=24) and a three-month wait-list (n=24) for patients with agoraphobia. After the waiting period, the 24 wait-list patients were randomized to TFT (n=12) or CT (n=12). The two treatment conditions were compared on three time points, pre-post treatment and at the 12-month follow-up, with 36 patients in each group. Assessments were performed pre-post treatment/waiting period and at the 12-month follow-up.

## 2.2 Patient samples

### 2.2.1 Recruitment and assignment

#### *Sample 1 (Paper I)*

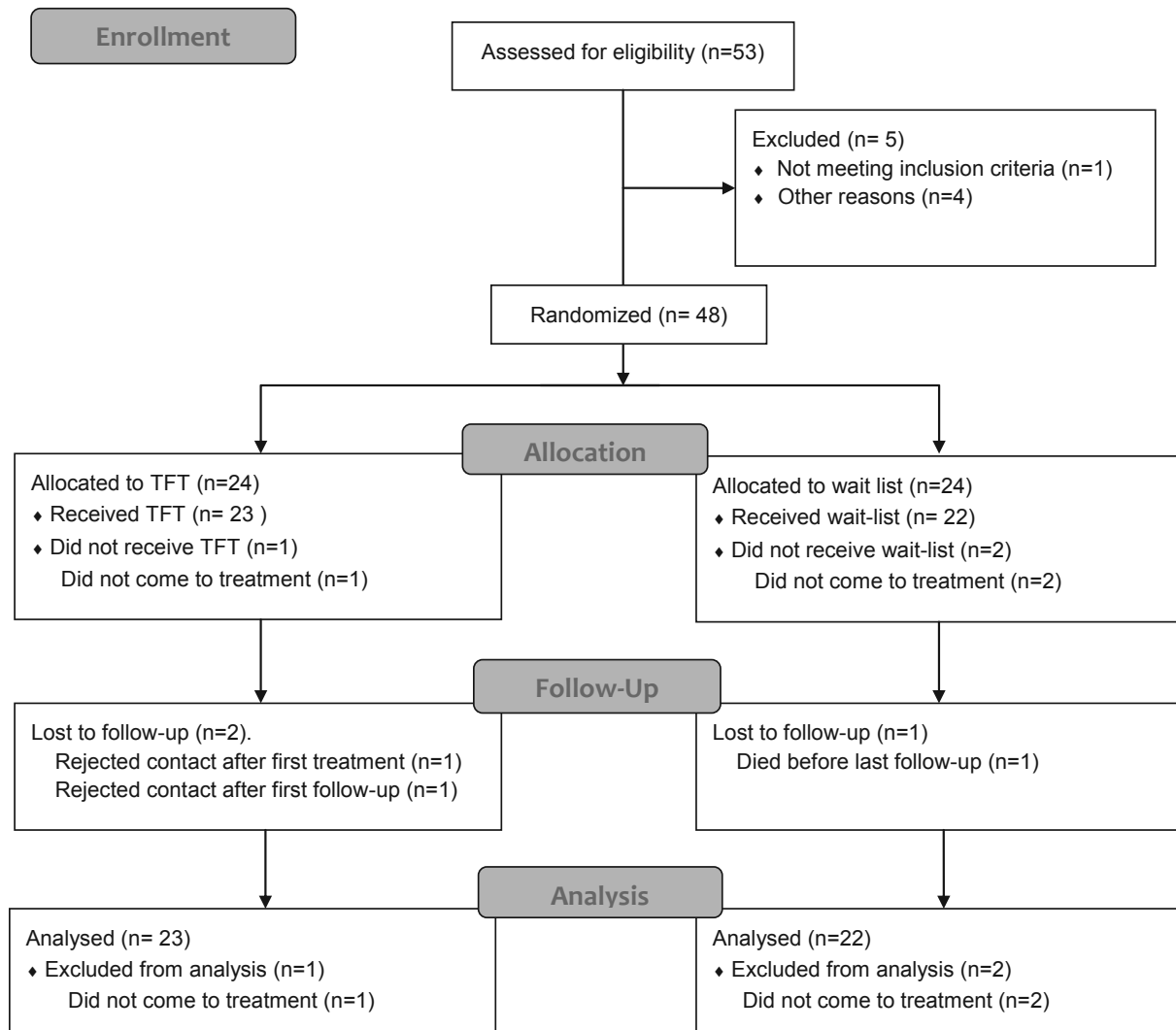
The recruitment process comprised written information provided by the study investigator (AI) to all therapists in the psychiatric wards and outpatient clinics as well as to general practitioners and private practicing psychologists and psychiatrists in the county of Aust-Agder (approximately 100 000 inhabitants), with a request to refer patients who suffered from agoraphobia, social phobia and/or PTSD to the research project. Fifty-three patients were consecutively referred over a period of 8 months in 2001-2 (Figure 1). One patient was symptom-free when the assessment period started, so 52 patients completed a diagnostic process with clinical evaluation, semi-structured interviews with the Mini-International Neuropsychiatric Interview (MINI) (D. V. Sheehan et al., 1998), the Iowa Personality Disorder Screen (IOWA) (Langbehn et al., 1999) and completed self-rating scales. An interview with the Structured Clinical Interview for DSM Personality Disorders (SCID II) (American Psychiatric Association, 1994) was performed if there was a positive answer to two or more items on items 1-6 of the IOWA.

Inclusion criteria were having one or more anxiety disorders and being willing to be randomized. Our only exclusion criterion was ongoing psychosis.

Four patients were excluded because they declined participation after evaluation. Three patients were first included, but then excluded from the analysis because they did not come to any treatment session. We have data for 7 of these patients; the data for the one who was symptom-free before study start are missing as she did not undergo the procedure of diagnosis and filling out self-rating scales. There were no statistically significant differences between these 7 and the 45 included patients for the demographic data described in Table 2.

**Figure 1**

**CONSORT 2010 Flow Diagram**



*Note: The figure was copied from Paper 1.*

**Sample 2 (Papers 2 and 3)**

Patients were primarily recruited from the catchment area for Sørlandet Hospital in the southern part of Norway, the counties of Vest-Agder and Aust-Agder with approximately a total of 270 000 inhabitants, between January 2007 and December 2008. The leaders of the hospital's six psychiatric outpatient clinics were informed both in writing and orally about the study, and were asked to refer patients to the principal investigator. News of the study was spread by word-of-mouth and through interviews in media.



The inclusion criteria were: (1) a principal diagnosis of agoraphobia with high level of agoraphobic avoidance, defined as a score  $\geq 2.5$  on the Mobility Inventory Alone (MIAAL) (Chambless, Caputo, Jasin, Gracely, & Williams, 1985). The agoraphobia could be in the form of either panic disorder with agoraphobia or agoraphobia without a history of panic disorder. (2) Being 18 years of age or older and (3) signed an informed consent. The exclusion criteria were: (1) moderate to high risk of suicide as measured by the MINI PLUS interview, (2) on-going substance abuse or dependence and (3) a history of psychosis.

A total of 208 patients were referred. Among these 136 were excluded for various reasons (Figure 2) and 72 were eligible for randomization. Among these, 21 patients (29%) were self-referred (CT n=12, TFT n=9), while 51 (71%) were referred from the six outpatient clinics or from their GP.

The 72 study patients were first randomly assigned to one of the three study conditions treatment with CT (N=24) or TFT (N=24), or a three-month wait-list (N=24). We received a randomization key from a statistician, made by the random number generator in SPSS, applying block randomization stratified by gender. A secretary kept the randomization key, concealed from all other study personnel and other co-workers. When the diagnostic procedure and blinded assessment had been completed for a patient, the principal investigator (AI) was informed of the treatment condition for that particular patient. After the waiting period, the wait-list patients (n=24) were again randomly assigned by an identical randomization procedure as previously described to either CT (N=12) or TFT (N=12).

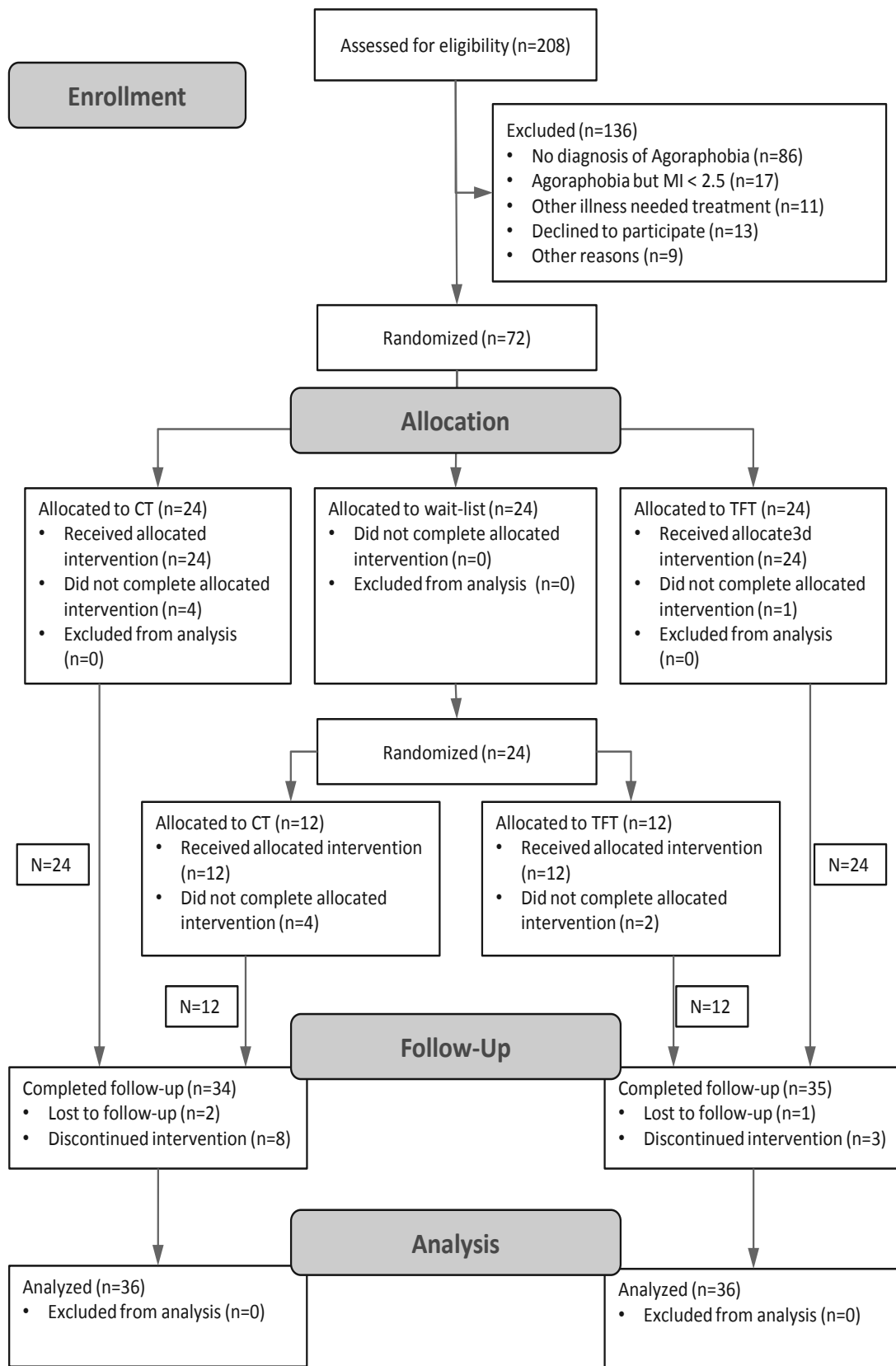
Patients were allowed to use any type of prescribed medication, although new medication prescribed for anxiety was not allowed to be initiated. Initially we intended that patients should not be allowed other medication changes than a lowering of dosage. Still, on the follow-up we learned that 9 patients had raised their dosage of psychotropic medicine. We decided to register and describe the changes that were reported by the patients rather than eliminating them from the statistical analyses, because we wanted the study to have clinical validity. Over the period of treatment and follow-up, the proportion of patients who changed the dosage of their psychotropic medication (n=27) did not significantly differ between patients receiving CT (n=15) or TFT (n=12). Furthermore, there were no significant

between-group differences regarding the proportion of patients lowering- (TFT n=8, CT n=10) or raising their dosage (TFT n=4, CT n=5). Statistical analyses of the primary effect variables for the 63 patients not reporting to have raised their dosage showed only small differences from analyses performed on all 72 patients.

The patients were requested not to seek additional treatment during the study period. For those that still sought such additional treatment, the type and frequency of the treatment was registered. The proportion of patients receiving additional treatment during the trial (n=14, 19%) did not significantly differ between the CT- (n=8) and the TFT (n=6) groups. Additional treatments were supportive therapy (CT=2, TFT=3), three-five extra sessions with their study therapist due to acute situations not related to their agoraphobia (CT=1, TFT=2), other therapist contact (CT=4, TFT=1) and acute inpatient care (CT=1).

Of the 72 patients included 11 (CBT = 8, 22%, TFT = 3, 8%, Fisher's exact test,  $p = 0.19$ ) dropped out of the treatment. The three TFT dropouts completed 3–4 of the 5 sessions while the 8 CBT dropouts completed 2–10 of the 12 scheduled sessions. Three (CBT = 2, TFT = 1) ended their therapy stating that they felt no need for further therapy. One TFT patient moved to another part of the country and a considerable symptom reduction was reported in the last of his three sessions.

Figure 2  
 Consort 2010 flow diagram for Sample 2



Note: The figure was copied from Paper 2.

## 2.1.2. Description of the patient samples

### *Description of Sample 1*

Patient characteristics are shown in Table 2

Table 2

#### Demographic data for Sample 1

Characteristic	Group	
	TFT (n = 23)	Wait-list (n = 22)
	M (SD)	M (SD)
Age at study start, years	36.6 (11.4)	37.4 (9.2)
Duration of symptoms, years	20.7 (10.5)	16.2 (10.2)
Number of anxiety diagnoses, mean	2.2 (0.8)	1.8 (0.7)
Number of other psychiatric diagnoses, mean	2.4 (1.4)	2.0 (1.5)
	N (%)	N (%)
Female	17 (74)	16 (73)
Number of patients diagnosed with one or more personality disorders	14 (61)	7 (32)
Number of patients using psychotropic drugs, all types	17 (74)	17 (77)
Number of patients using benzodiazepines	9 (39)	6 (27)
Number of patients using antidepressants	11 (48)	13 (59)
Number of patients receiving additional psychotherapy	9 (39)	6 (27)

*Note.* Relevant tests revealed no significant ( $p > 0.05$ ) differences between the two groups, although for personality disorder the  $p$ -value was 0.051.

#### Demographic and clinical characteristics

Age of the patients at study start ranged from 19 to 60 (TFT=23-57, wait-list=19-60), with a mean of 37.0 (TFT=36.6, wait-list=37.4) and a median of 36

(TFT=32, wait-list=36). Duration of symptoms varied from two to 45 years (TFT=7-45 years, wait-list=two -42 years). The median duration was 16 years (TFT=17, wait-list=14), and the mean duration was 18.5 years (TFT=20.7, wait-list=16.2).

### Comorbidity

These patients suffered from a variety of diagnoses. Their primary diagnosis for treatment was decided as the one most disabling, and was then chosen as the main target for treatment. These primary diagnoses were social phobia (n=16), panic disorder with agoraphobia (n=16), PTSD (n=8), agoraphobia without history of panic disorder (n=4) and generalized anxiety disorder (GAD) (n=1).

Comorbid anxiety diagnoses were social phobia (n=14), panic disorder with agoraphobia (n=12), PTSD (n=4), agoraphobia without a history of panic disorder (n=2), GAD (n=6), panic disorder without agoraphobia (n=2), obsessive compulsive disorder (n=8), and specific phobias (n=6). The majority had more than one anxiety disorder, and 34 had a diagnosis of current major depression.

Twenty-one patients had one (n=11) or more (two n=8, three n=1, four n=1) personality disorders (PD). The far most common was avoidant PD (n=16), followed by paranoid PD (n=5), borderline PD (n=3), obsessive compulsive PD (n=3), PD not otherwise specified (NOS) (n=3), dependent PD (n=2), and schizoid PD (n=1).

Three patients were diagnosed with alcohol dependence, two with alcohol abuse, one with opioid dependence and one with bulimia nervosa.

### *Description of Sample 2*

Patient characteristics are shown in Table 3

Table 3

#### Demographic data for Sample 2

Characteristic	Group	
	TFT (n = 36)	CT (n = 36)
	M (SD)	M (SD)
Age at study start, years	39.1 (12.2)	36.9 (12.7)
Duration of symptoms, years	11.8 (8.8)	13.5 (12.2)
Number of Axis I diagnoses, mean	2.1 (1.4)	2.5 (1.4)
	n (%)	n (%)
Female	27 (75)	27 (75)
Cohabiting	29 (81)	21 (58)
Low work status	18 (50)	10 (28)
Affective disorder, current	8 (22)	13 (36)
Affective disorder, lifetime	21 (58)	26 (72)
One or more anxiety disorders, in addition to agoraphobia with/without panic disorder	15 (42)	16 (44)
Abuse of alcohol or drugs, lifetime	4 (11)	3 (8)
One or more personality disorders	9 (25)	5 (14)
Regularly use of benzodiazepines	4 (11)	4 (11)
Benzodiazepines use on demand	6 (17)	8 (22)
Use of antidepressants	21 (58)	20 (56)

*Note.* Low work status=being on sick leave for more than one year or receiving permanent disability pension. Affective disorder includes major depressive episode, recurrent depression, the depressive phase of bipolar disorder type 2 and dysthymia. There were no significant ( $p<0.05$ ) differences between the two groups

### Demographic and clinical characteristics

The patients' age at study start ranged from 18 to 71 (CT=19-71, TFT=18-61), with a mean of 38.0 (CT=36.9, TFT=39.1) and a median of 38 (CT=35, TFT=39). Fifty-four women (75%) and 18 men were included in the study. The gender distribution was similar for CT and TFT, as the randomization procedure was stratified by gender. We did so because we expected notably more women than men to be included (Kringlen, Torgersen, & Cramer, 2006), and wanted to be sure that we got no bias from a different sex distribution between the two treatment conditions.

Duration of symptoms varied from 4 months up to 56 years (CT=4 months-56 years, TFT=6 months -37 years). The longest duration of 56 years represented the oldest person in the study, having had symptoms of panic and agoraphobia from the age of 15. The median duration was 10 years (CT=11, TFT=10), and the mean duration was 12.6 years (CT=13.5, TFT=11.8).

### Comorbidity

As in Study 1, also the patients in Study 2 had a substantial burden of comorbidity as shown in Table 2. The proportion of comorbid anxiety disorders did not differ significantly between treatment groups (CT=16, TFT=15,  $p=0.81$ ). The comorbid disorders were; social phobia ( $n=16$ ) (CT=6, TFT=10,  $p=0.26$ ), specific phobia ( $n=6$ ) (CT=3, TFT=3), OCD ( $n=2$ ) (CT=2, TFT=0,  $p=0.15$ ), PTSD ( $n=3$ ) (CT=1, TFT=2,  $p=0.56$ ), and GAD ( $n=14$ ) (CT=10, TFT=4,  $p=0.07$ ).

As many as 47 of the 72 patients (65%) had a lifetime history of affective disorders, 26 in the CT group and 21 in the TFT group ( $p=0.22$ ). Twenty-one (29%) had a current diagnosis of affective disorder at study start (CT=13, TFT=8,  $p=0.20$ ).

Current affective disorders comprised: major depression ( $n=7$ ) (CT=5, TFT=2), on-going recurrent major depression ( $n=8$ ) (CT=6, TFT=2), dysthymia ( $n=3$ ) (CT=1, TFT=2), and depressive phase of bipolar type II disorder ( $n=3$ ) (CT=1, TFT=2). Affective disorders in remission comprised major depression ( $n=10$ ) (CT=6, TFT=4) and recurrent major depression ( $n=16$ ) (CT=7, TFT=9).

Seven patients reported a lifetime abuse of alcohol or drugs (CT=3, TFT=4,  $p=0.69$ ). Of these, one CT patient reported some symptoms of alcohol abuse in the last year before study start. Since he did not fulfill the criteria for current alcohol or drug dependence he was not omitted from the study.

Fourteen patients had an axis II diagnosis on inclusion (CT=5, TFT=9,  $P=0.23$ ). The types of PDs were; avoidant PD ( $n=4$ ) (CT=0, TFT=4,  $p=0.04$ ), dependent PD ( $n=1$ ) (CT=0, TFT=1,  $p=0.31$ ), paranoid PD ( $n=1$ ) (CT=1, TFT=0,  $p=0.31$ ), and PD not otherwise specified ( $n=9$ ) (CT=4, TFT=5,  $p=0.76$ ).

### Participants vs. non-participants

For the 135 patients that were excluded from the study, we only have data for the reason for exclusion (Figure 2), age and gender at assessment. Mean age at assessment for the excluded patients was 39.1 (SD=12.3), whereas mean age for the 72 study patients was 38.0 (SD=12.4). Sixty-six per cent of the excluded patients and 75% of the study patients were female, which is a non-significant difference ( $p=0.21$ ).

## 2.2 Procedures

### 2.2.1 Procedures for Study 1

Following inclusion, all patients were randomized to treatment or a waiting period, based on a computer-generated list. The administrative procedures were performed by AI, therefore the randomization list was open to him, but since patients were included consecutively, this was not a source of bias.

A psychiatric resident (Eva Cecilie Orvin) performed diagnostic assessments for 11 patients, except from the SCID II interviews, after supervision. For those of her patients who scored positively on two or more of the items 1-6 on the IOWA, a SCID II interview was performed by AI who also performed the diagnostic assessments for the remaining 41 study patients.

The diagnostic procedures for all study patients were performed during May and June in 2002. Patients who were randomized to TFT in the first part of the study got two treatment sessions during one week in late June (week 24). The first session lasted up to 50 minutes, and was given on Monday, Tuesday or Wednesday in week 24. The second session lasted up to 25 minutes, and was given during Thursday or Friday of that week. For most patients, AI sat beside and observed the therapy, and made notes for the patient's psychiatric journal. Twenty-seven patients were individually scheduled for two TFT treatments by Mats Uldal during these five days.

Two weeks after this treatment week, all patients in the TFT group met with AI to fill in scales of symptoms and function. Then both the patients who had received TFT, and the patients on the wait-list, were re-assessed after two



and a half months in August 2002. Following this assessment, those in the wait-list group got similar treatment with Mats Uldal. This delayed-treatment group was then assessed by AI within two weeks after they had received treatment.

All patients in both groups were assessed in November and December 2002. For the group that had received TFT in August, after a waiting period, this represented a three-month follow-up. For the group that had received TFT in June, this was a 6-month follow-up. We did not include the results from this 6-month follow-up in the statistical analyses, because this 6-month assessment was done only for the patients who received treatment in June. Finally, all patients had a 12-month follow-up from June to September 2003.

### **2.2.2 Procedures for Study 2**

The 72 patients were consecutively included in the study. After having filled in self-assessment questionnaires, completed the initial diagnostic interviews and signed the informed consent, they had an interview with one of the blinded assessors, using the ADIS interview for panic disorder and agoraphobia. They were then randomized, and started on the waiting period or treatment as soon as possible. For the majority of the patients the therapy began within the first two weeks after randomization. By the end of the three-month waiting period, or within 2-3 weeks after having ended therapy, they had an assessment with one of the blinded interviewers and filled in self-assessment questionnaires. The waiting group were then randomized to CT or TFT, and re-assessed post-treatment. Twelve months after the end of therapy, all patients had their last follow-up. They went through an ADIS interview with the blinded interviewer and filled in symptom scores. They also had a final session with AI comprising a re-diagnostic procedure applying the MINI PLUS and the SCID II; in addition they were asked about any side effects of the therapy and about their opinion about having participated in the scientific study. The study was conducted from January 2007 to September 2010.

## **2.3 Assessments**

### **2.3.1 Diagnostic interviews**

Mental disorders were classified according to DSM-IV (American Psychiatric Association, 1994). For this purpose we used the semi-structured interviews Mini-International Neuropsychiatric Interview (MINI) version 5.0.0 (D. V.

Sheehan et al., 1998) for Sample 1, and the MINI PLUS version for Sample 2. The MINI covers mood disorders, anxiety disorders with the exception of specific phobias, substance-related disorders, eating disorders, schizophrenia and other psychotic disorders, while the MINI PLUS also includes specific phobias, somatoform disorders, ADHD and premenstrual dysphoric disorder. We chose to use the MINI for the first study because this was an established practice in the out-patient clinic in which the study was performed. Thus the evaluator (AI) had an extensive competency with MINI assessments (N=3-400). Furthermore the MINI and MINI PLUS have been used in research studies in this field (Meulenbeek et al., 2010). We applied MINI PLUS for the second study because it is more comprehensive than MINI, but it was not available in 2001. A study on the Norwegian version of MINI for inpatients found a test-retest agreement of 84 % for agoraphobia, a Cohen's kappa of 0.67 was reported which is considered good (Mordal, Gundersen, & Bramness, 2010).

To screen for personality disorders in Sample 1, we applied the Iowa Personality Disorder Screen (IOWA) (Langbehn et al., 1999), which consists of 11 items. We used a cut-off of two positive answers on items 1-6 according to the recommendations of Langbehn et al, which they found yielded a sensitivity of 96%. The Norwegian version has been valued as a useful screening instrument for personality disorders in an outpatient clinical setting (Olsson, Sørebo, & Dahl, 2011).

In the 21 patients who screened positive on the IOWA, the SCID II interview was applied to diagnose DSM-IV personality disorders (American Psychiatric Association, 1994). This semi-structured interview consists of 94 items, which cover the diagnostic criteria for 10 personality disorders. Four or five of the items for each disorder must be scored as positive to fulfill the criteria of a specific diagnosis, except for antisocial personality disorder, in which a positive score on three items before the age of 15 and three items after the age of 15 must be present for the diagnostic criteria to be fulfilled. A diagnosis of personality disorder not otherwise specified (NOS) is established when a patient scores positively on items from more than one personality disorder but not sufficiently for a specific PD, and the symptoms are evaluated as having marked influence on daily life and functioning. A psychometric study of the properties of SCID II for DSM-IV concluded that it had adequate

reliability both for inter-rating and for internal consistency (Maffei et al., 1997). All patients in Sample 2 were interviewed with the SCID II.

### 2.3.2 Self-report questionnaires for Sample 1

#### *Symptom Checklist 90-Revised (SCL-90) (Derogatis, 1977)*

The primary outcome variable in the first study was the global symptom index, *GSI*, which is the mean score of the SCL-90-R (Derogatis, 1977). The SCL-90-R consists of 90 items, with a five-point Likert scale for each item (0-4, 0 denoting *not at all* and 4 *extremely*), and is divided into 9 subscales. We chose *GSI* as the primary outcome variable in Study 1 because we had applied it as a measure at admission and of treatment outcome at discharge and two years follow up in all patients at our ward for 10 years. The *GSI* has been shown to be both a valid and reliable measure of general mental distress and is widely used for clinical and scientific purposes (Cyr, McKenna-Foley, & Peacock, 1985; Rauter, Leonard, & Swett, 1996). Vassend et al reported an excellent internal consistency of a Norwegian version of the SCL-90-R with a Cronbach's alpha of 0.97 for the *GSI* (Vassend, Lian, & Andersen, 1992). A recent Norwegian report states that the SCL-90-R is well designed for assessing changes in overall distress, which corresponds to our use of the instrument (Siqueland, Moum, Leiknes, & Folkehelseinstituttet, 2016). In our study we found a Cronbach's alpha of 0.93.

#### *Hospital Anxiety and Depression Scale (HAD) (Zigmond & Snaith, 1983)*

The HAD contains 7 items on anxiety and 7 on depression, each item is scored on a four-point scale with a score of 0 denoting no symptom to 3 denoting that the symptom is large, or that it is present very often or most of the time, depending on the item's text (Zigmond & Snaith, 1983). It has been reported to be sensitive to changes in a treatment study of anxiety disorders (Johnston, Pollard, & Hennessey, 2000). A Norwegian version was used in the large Nord-Trøndelag health study (HUNT), Mykletun et al reported an acceptable Cronbach's alpha of 0.80 for the anxiety scale and 0.76 for the depression scale (Mykletun, Stordal, & Dahl, 2001).

#### *Sheehan's disability scale (SDS) (Leon, Olfson, Portera, Farber, & Sheehan, 1997)*

The SDS measures level of impairment on a visual linear scale with 11 points (0-10) on three items; work, social life and leisure activities, and family and domestic work (Leon et al., 1997). The value of 0 means *no*, 1-3 *mild*, 4-6

*moderate, 7-9 marked and 10 extreme disability.* Sheehan and Sheehan have reported that this scale is increasingly used in clinical trials, and that their results indicate that the SDS is sensitive to change, at least following pharmacological treatment (K. H. Sheehan & Sheehan, 2008). Leon et al reported a good Cronbach's alpha of 0.89 (Leon et al., 1997).

### **2.3.3 Therapist interviews for Sample 2**

The Anxiety Disorders Interview Schedule (ADIS) (DiNardo, Brow, & Barlow, 1994) was developed as a semi-structured interview to ascertain more reliable diagnoses for anxiety, somatoform and affective disorders, in the version for DSM-IV it also comprises assessment of substance abuse disorders, and lifetime diagnoses in addition to current diagnoses. The ADIS consists of a comprehensive diagnostic interview for each specific disorder, and for several sections it has a severity rating scale from 0 (*none*) to 8 (*very severe*) to measure the degree of symptoms and functional impairment. Furthermore, it has two questions about the degree of distress and influence from the disease as perceived by the patient. The ADIS version for agoraphobia has dimensional scores for situational ratings. These consist of 22 items describing situations that are often avoided by patients with agoraphobia, such as driving local or long distance, visiting grocery stores, being at home alone. Each item has a score for apprehension/anxiety and a score for avoidance, with a rating scale from 0 to 8, with 0 meaning no avoidance or apprehension and 8 denoting the most severe avoidance or apprehension. These two scales constitute the two primary outcome variables of this study, and have been applied by other researchers in the field of agoraphobia (Craske, DeCola, Sachs, & Pontillo, 2003).

We used the adult version for DSM-IV, the ADIS-IV-L. The English version was translated into Norwegian and then translated back into English. The final translation was discussed with and approved by the principal supervisor of the study (Professor Asle Hoffart).

At the time of inclusion the interviewers applied the full version. When re-administered after wait-list or treatment and at follow-up, they used an abbreviated version in which the diagnostic parts were omitted. Due to practical reasons, 47 of the 227 ADIS interviews were performed by the principal investigator (AI). When rescored from video by two of the primary interviewers (ES, VØH) who were blinded to the scores of AI, the intra-class

correlation (ICC) was 0.94 (CI 0.90 – 0.97). These results compare well with those found by Brown et al. (Brown, Di Nardo, Lehman, & Campbell, 2001), who reported a Pearson's *r* of 0.86 for the reliability of rating of agoraphobic avoidance from the ADIS.

The diagnosis of agoraphobia in our study was based on the MINI PLUS. We would have reconsidered the agoraphobia diagnosis if the results of the corresponding ADIS interview had raised any concern about diagnostic assessment. There was no doubt for any patient, maybe because we required a high cut-off score on the MIAAL for study inclusion.

In conclusion: We applied the ADIS interview to 1) secure a correct diagnosis of agoraphobia, 2) establish the primary outcome scores on avoidance and anxiety/apprehension, and 3) establish two of the secondary outcome scores, the degree of interference in daily life, and the degree of distress due to avoidance and apprehension.

#### **2.3.4 Self-report questionnaires for Sample 2**

##### ***Mobility Inventory (MI) (Chambless et al., 1985)***

The MI has 26 items which are scored on a 1 (*do never avoid*) to 5 (*do always avoid*) scale. It consists of two scales, Avoidance Alone (MIAAL) and Avoidance Accompanied. We report only scores from the MIAAL, as being accompanied by a trusted person is a safety strategy in agoraphobia (A Wells, 1997), and one of the criteria in the MINI PLUS interview for the diagnosis of agoraphobia (D. V. Sheehan et al., 1998). A high internal consistency score with  $\alpha=0.96$  was reported for the MIAAL (Chambless et al., 2011). In our study we found a Cronbach's alpha of 0.97.

In our study we used a MIAAL score above 2.5 or higher as an inclusion criterion. This value was chosen to be certain that all patients included had severe agoraphobia, as with such a score the specificity for diagnosis of agoraphobia is 1.0 (Dianne Chambless, personal communication).

##### ***Beck Depression Inventory (BDI) (A. Beck, Ward, Mendelson, Mock, & Erbaugh, 1961)***

To assess the severity of depressive symptoms and how patients changed during therapy and follow-up we applied the BDI (A. Beck et al., 1961). The BDI is a self-report 21 items inventory, each item is scored on a 0 (*no symptoms*) to 3 (*severe symptoms*) scale. It is widely used both for research and clinical

purposes with a high internal consistency of  $\alpha=0.86$  for populations with mental disorders being reported (A. Beck, Steer, & Carbin, 1988). A study from a general population sample stated a good internal consistency with Cronbach's  $\alpha=0.91$  (Aasen, 2001). In our study Cronbach's  $\alpha$  was 0.93.

***Beck Anxiety Inventory (BAI) (A. Beck, Epstein, Brown, & Steer, 1988)***

To assess the level of anxiety we applied the BAI (A. Beck, Epstein, et al., 1988). This is a self-report scale with 21 items, the items are rated on a four-point scale from 0 (*not at all*) to 3 (*severely, I could barely stand it*). Beck et al reported a high internal consistency of  $\alpha=0.92$ , and good test-retest reliability over one week (A. Beck, Epstein, et al., 1988). In our study Cronbach's  $\alpha$  was 0.96.

***Agoraphobic Cognitions Questionnaire (Chambless, Caputo, Bright, & Gallagher, 1984)***

The Agoraphobic cognitions questionnaire (ACQ) consists of 14 items assessing frequency of agoraphobic thoughts, scored on a 1-5 scale, from 1 (*thought never occurs*) to 5 (*thought always occurs*), and 14 items on the degree of belief in the same thoughts, scored on an eleven point scale ranging from 0% (*do not at all believe*) to 100% (*totally convinced*) (Chambless et al., 1984). Chambless et al report that the 14 item scale on degree of beliefs was stable on two separate scores pretreatment, with an average interval of 8 days. We found a Cronbach's  $\alpha$  of 0.87 for the ACQ frequency scale and 0.88 for the belief scale.

***Body Sensations Questionnaire (BSQ) (Chambless et al., 1984)***

The BSQ consists of 17 items on bodily sensations that may arise in a fearful situation (Chambless et al., 1984). It measures how afraid the patient is of each of these sensations. Each item is scored on a five point scale from 1 (*not frightened or worried by this sensation*) to 5 (*extremely frightened by this sensation*). Chambless et al reported highly internal consistency of the BSQ with a Cronbach's  $\alpha=0.87$ . In our study Cronbach's  $\alpha$  was 0.94.

**2.3.5 Assessment of CT therapists' competence**

The supervisors scored 15 of the 20 supervised sessions using the Cognitive Therapy Scale (CTS) (Westra, Constantino, Arkowitz, & Dozois, 2011; Young & Beck, 1980). We applied the 16 items version with item scores on a scale of 0-6, with 0 denoting "bad, or failing to achieve the goal", 2 "mediocre", 4

“good” and 6 “an excellent achievement”, except for item 15 where the scale was 0-4 and items 12 and 13 where the score was Yes/No. If yes on item 12 there was an additional numerical score with a 0-6 point scale. Items 1-6 scored general therapeutic skills, while items 7-11 scored conceptualization, strategy and technique. Item 12 asked if specific problems arose between patient and therapist, and if yes how successful the therapist was in handling them, and item 13 asked if any deviations from the CT were judged as justified. Item 14 scored an overall rating. Item 15 assessed whether you would select this therapist if conducting an outcome study of cognitive therapy for agoraphobia, assuming the session was typical, with 0 denoting “clearly no”, 1 “probably no”, 2 “uncertain”, 3 “probably yes” and 4 “clearly yes”. Item 16 scored how difficult the patient was to work with, with 0 denoting “not at all”, 3 “moderately” and 6 “extremely difficult”.

## **2.4 Interventions**

### **2.4.1 Thought field therapy.**

Thought field therapy (TFT) was the first of the energy psychology treatments (Feinstein, 2008). Basically it consists of patients tapping sequences of acupuncture points while keeping in mind the thought and feelings connected to the symptom/problem that is troubling them. Over the years following the beginning of TFT, Callahan tested sequences of points to tap according to what kind of problem or symptom the patients presented, and called them algorithms. As an example, if a patient presents with anxiety, the algorithm says that the patient shall first tap 5 – 10 times on a point between the eyebrows, then just beneath one of the eyes, on one of the sides of the body, and lastly on a point that lies just aside the sternum and beneath the clavicle, regardless of which side of the sternum. The tapping should be performed firm but gentle, so that it is clearly felt, but does not give any bruises (Callahan & Turbo, 2001).

A typical TFT session starts with the therapist asking the patient what is troubling him or her most, and what the patient hopes to achieve in the session. If it is the first time the specific problem is addressed, the therapist will normally ask for the first memory of this or a closely related problem and treat that first. Usually the patients do the tapping. Sometimes they can be overwhelmed by emotions, so that it is necessary that the therapist does the tapping in that part of the session. Before tapping the therapist asks the patient

to give a 0 (*no upsetting feeling or thought*) to 10 (*worst ever*) score on subjective units of discomfort (SUD) (Callahan & Trubo, 2001). When the sequence of acupoints, the algorithm, has been tapped, the therapist asks the patient again for a SUD score. If it is reduced with at least two points, the patient is asked to repeat the tapping sequence, and again to report a SUD. This is repeated until the SUD score is down to a score of one or preferably zero.

If the SUD is not reduced by at least two points, the procedure is expanded. After a first round of tapping the points in the prescribed sequence, the patient performs a procedure called 9-gamut (Callahan & Trubo, 2001), which consists of eye movements, humming and counting while a specific acupoint on the hand is tapped. Then the patient repeats the sequence of acupoints, and is again asked for a SUD score.

If the reduction of SUD still is lacking, the TFT theory says that this may be due to what Callahan called a psychological reversal. To correct this, the patient is instructed to tap on the edge of the little finger side of one of the hands, sometimes called the karate point to make it easy to remember, and then repeat the whole algorithm with tapping the sequence of acupoints twice with the 9-gamut in between, and then give a SUD score.

After having successfully treated the memory of the first incident, the therapist might ask for the last time this represented a significant problem, and treat that using the same procedures. At the end of the session, the therapist will ask for a situation where the problem is anticipated to be troubling the patient, preferably at a specific date and place, and treat that.

We wanted to make the TFT modality as simple as possible. Therefore we chose not to use some of the additional features of the method, such as a test procedure from kinesiology to decide which acupoints to tap and in which order, or procedures to block the negative effects of what Callahan called toxins (Callahan & Trubo, 2001), even if some proponents of TFT might say that these procedures would have given better results than the use of TFT algorithms only that we applied. In the two studies in this dissertation, TFT was applied only at the algorithm level.



## *TFT therapists and therapeutic integrity*

### Study 1

In the first study, TFT was performed by Mats Uldal. He was educated from The Norwegian University of Sport and Physical Education, and had worked for about 20 years with motivational psychology in different sports. Having heard about TFT, he went to USA and learned it from Roger Callahan in 1997. After returning to Norway he started to apply TFT in his motivational work, and shortly thereafter he began to educate both health professionals and lay therapists in this method. In this study, AI was present in most parts of all the therapeutic sessions, partly to assure that Uldal applied TFT and no other therapeutic interventions during the treatment.

### Study 2

In the second study, the TFT therapist was Anne Trine Eia. She had five years of experience as a TFT therapist, and background as a teacher, but no formal health education or therapeutic experience other than that of being a TFT therapist. In particular, she had no experience with CBT. Based on Callahan's manual for anxiety disorders and panic attacks, she constructed a TFT manual in Norwegian specific to agoraphobia (Eia, 2012). The manual describes in detail how the TFT therapist guides the patient to target the memories and other thoughts that trigger maximum anxiety, and prescribes the specific sequence of acupoints to be tapped by the patient or therapist. This manual was discussed with both the study's principal supervisor (Asle Hoffart) and AI. AI supervised Eia during the study to ensure adherence to the manual, as well as to ensure that she did evaluations of the risk of suicide and other issues on patient safety.

We wanted to perform the TFT as close to ordinary practice for TFT as possible. A set of five sessions was usual among TFT therapists (Holmaas, 2017; Uldal, 2007), so we chose this for the second study.

Early- or middle-phase sessions with 9 individual patients were videotaped, and then evaluated by another experienced TFT therapist, Stein Lund Halvorsen, who was familiar with the agoraphobia manual. There is no systematic treatment fidelity instrument developed for TFT. Lund Halvorsen confirmed that the content of the TFT treatment was in accordance with standard TFT content and procedures on the algorithm level, in all nine videotaped sessions.

#### **2.4.2 Cognitive therapy.**

Cognitive therapy (CT) and Cognitive behavior therapy (CBT) are among the leading psychotherapies for anxiety disorders, and their efficacy is studied in numerous controlled trials (Norton & Price, 2007). In the CT arm of Study 2, we used a manual for individual treatment of panic disorder with or without agoraphobia created by David M Clark (Hawton et al., 1989). The treatment consisted of 12 sessions with a sequence of therapeutic tools. The first sessions were spent on elaborating the panic circle for the specific situations leading to panic attacks for the given patient. This thorough work is intended to establish a common understanding for patient and therapist on the details of catastrophic thoughts, anxiety feelings and safety strategies, which are parts of the panic attacks that the patient has experienced.

The next step is to teach the patients about bodily reactions in a panic attack. In the frame of CT, this may be done by asking the patient what is needed of bodily reactions to survive a true catastrophic situation, using a flipover chart to draw a human being and a scary animal, e.g. a roaring lion. Often the patient, when asked, knows that adrenalin is a central hormone in this process of fight or flight. The therapist connects this knowledge to information on how central parts of the brain react to perceived danger without contacting the reflecting frontal part of the brain, and demonstrates how a reflective stance may become lethal when the lion is nearby. We often use a concept of “alarm button” to illustrate the speedy and reflexive nature of the panic reaction.

Usually, patients find this part engaging and often amusing, which is a good common ground for patient and therapist for the next therapeutic step. The therapist goes back to the patient’s belief that his/her panic symptoms mean that he/she is going to die or experience another bodily catastrophic event, especially when the panic attack is ongoing. The therapist acknowledges that this is a plausible belief in such a situation. Then the therapist asks, in light of their discussion on the meaning of bodily symptoms during perceived danger, if by any means the patient’s panic symptoms could mean that he/she was experiencing a panic attack? This should be done cautiously, in a manner that prevents the patient from thinking that the therapist does not believe in him/her. We can call the prime belief of panic symptoms being signs of death

or another catastrophe Theory A, and the faint possibility that these symptoms may indicate a panic attack Theory B.

So then, how do we deal with these two opposing theories? As a CT therapist, one wants to establish patient and therapist as a research team, with the patient as a specialist on him/herself, and the therapist as specialist on methods for beneficial change. In this frame, the task for them is to find a situation where Theories A and B can be tested. As a specialist on him/herself, the patient is asked to suggest situations which may be suitable for a test. The therapist's task is to modify the situation to make the experiment a likely success. They set up a prediction regarding what the patient believes will happen in terms of a catastrophic result, and rate to what degree (0-100%) the patient believes that this catastrophe is likely to happen. The experiment is then performed, and is afterwards studied in detail, relating the result to the prediction. Patient and therapist together make conclusions that they both agree upon regarding this specific experiment, and the therapist should be cautious not to draw hasty conclusions regarding future situations. Rather, the therapist should ask the patient about what is needed to be tested next, and then they plan together a new experiment to be performed. A main purpose of experiments is to evoke the strong symptoms of the patient's panic attacks, often hyperventilation to evoke feelings of dizziness and related thoughts about fainting and even dying.

The aim of this therapy is that through these experiments, followed by a thorough analysis each time relating to the patient's original belief of bodily disaster, the patient will see that natural bodily reactions to a perceived danger may be a more probable explanation of what he/she feels, rather than his/her catastrophic beliefs of soon going to die.

### *CT therapists and training*

The two CT therapists were experienced psychiatrists with formal training and certification in CT. During the year before study start, they were both trained in using the CT manual for agoraphobia and panic disorder by two experienced cognitive therapists and researchers who have PhDs on agoraphobia (Asle Hoffart) and social phobia (Finn-Magnus Borge). During this period, the therapists received biweekly feedback by phone on videos of therapy sessions. The supervision continued into the early phase of the

study, during which each therapist received feedback on 10 videotaped study sessions.

### *Treatment integrity for the CT*

Seven sessions from the starting phase and eight from the mid-phase were assessed using the Cognitive therapy scale (CTS) (Young & Beck, 1980), which has been shown to be sensitive to variations in the quality of the therapy (Vallis, Shaw, & Dobson, 1986). The therapists were scored as being good on the items of general therapeutic skills, mean 4.0 (range 3.2-4.8), as well as on the items of conceptualization, strategy and technique, mean 4.0 (range 2.6-5.0). In none of the sessions specific problems between patient and therapist were rated to occur. The sessions were rated as not involving deviations from CT. Mean score on the overall rating was 3.9 (range 2.5-5.0), a score of 4 again describing the therapist as good. On the question about choosing this therapist for a new study the mean score was 3.0 (range 1.0-4.0), which means a likely “yes”. For the rating of how difficult the patient was to work with the mean was 1.4 (range 0.0-4.0), denoting a level midway between not at all and moderately difficult. The evaluation of patients being not so difficult to work with is a bit puzzling in view of their high scores on the Mobility inventory (MI).

## **2.5 Statistical analysis**

We used the SPSS software to perform the statistical analysis in all studies, starting with version 12 and ending with version 23.

### **2.5.1 Statistical analyses for Paper 1**

We applied independent samples t-tests and Chi-square tests to compare demographic data for the TFT group and the wait-list group. Repeated measures ANOVAs were used to compare the two groups, as well as to evaluate the total sample at pretreatment and at follow-ups, applying simple contrast (Winer, 1971). The effect sizes (Cohen’s *d*) were calculated using a pooled standard deviation for pretreatment at the three follow-ups. One commonly classifies effect sizes calculated with Cohen’s *d* as no (0–0.2), small (0.2–0.5), medium (0.5–0.8), and large effects (>0.8) (Opris et al., 2012). We applied the principle of intention to treat for all analyses. For missing values we used the principle of last observation carried forward (LOCF) analysis.

### 2.5.2 Statistical analyses for Paper 2

In planning the study, a power analysis for a non-inferiority study was conducted with assistance of a statistician. We assumed 70% effectiveness for CT and 85% for TFT. To obtain 80% statistical power with 90% confidence intervals and a non-inferiority delta limit of 10%, sample size calculations showed that 34 patients were needed in each group. As both the criteria for estimating effectiveness for TFT and the non-inferiority margin for scores on the ADIS avoidance and anxiety scales are highly uncertain, we presented our findings as a conventional superiority trial with two-sided statistical tests using 5% significance level. In this switching from a non-inferiority to a superiority design, we followed guidelines established by The Committee for Proprietary Medicinal Products (CPMP) (Products, 2001), although there was no evidence of superiority of TFT over CBT. For statistical comparisons of demographic data between the two groups we used the independent sample's t-test for continuous data and the Fisher's exact test for categorical data.

First we analyzed pre-post treatment on the three conditions wait-list (n=24), CT (n=24) or TFT (n=24). After treatment of the wait-list patients we analyzed the two conditions CT (n=36) and TFT (n=36) pretreatment, post-treatment and at 12-month follow-up. For both calculations we used repeated measures ANOVAs (Winer, 1971), and to calculate the effect sizes we used G\*Power 3<sup>20</sup> (Faul, Erdfelder, Lang, & Buchner, 2007).

Because there were some differences in the pretreatment measures for the CT and the TFT groups, we did ANCOVAs on the two treatment groups (CT=36, TFT=36) with pretreatment values for the primary effect variable of avoidance as a covariate. As in Study 1 we used the principle of LOCF analysis for missing values.

We used Cronbach's alpha to estimate the internal consistency (reliability) of our continuous outcomes. A value of 0.8 or higher is generally considered acceptable, but with the caution that a large number of items in itself increases Cronbach's alpha (Field, 2005). To test the interrater reliability on the primary effect variables from ADIS we used the intra-class correlation coefficient (ICC) (Laake, Olsen, & Benestad, 2008). Laake et al stated that an ICC score of 0.6 to 0.9 is very good and 0.9 to 1 nearly perfect.

### **2.5.3 Statistical analyses for Paper 3**

We used Chi-square and independent sample's t-test for statistical comparisons between the two groups for categorical and continuous variables, respectively (Table 1).

We analyzed four potential predictors/moderators using multiple linear regression analyses with the difference in scores pre-post treatment and pretreatment to 12-month follow-up on the ADIS avoidance scale as the dependent variables. We controlled for baseline values using pretreatment ADIS avoidance scores as a covariate, and we used hypothesized predictors and type of treatment (TFT/CBT) as independent variables. Main effects of predictors and type of treatment were tested without the interaction term included in the model. Two-way interaction terms were entered one at a time in the equation when testing for potential moderation.

## **2.6 Ethics and study approvals**

### **2.6.1 Ethics and study approval for Study 1**

The study was approved by the Regional committee for medical and health research ethics (REK) Region south at May 10<sup>th</sup> 2001 (REK ref. no: S-01107). All patients got verbal and written information about the study, and signed a formal consent to participate. The study was registered in the ClinicalTrials.gov with the number NCT00202709.

If needed, the study participants were offered further help or referral to another therapist after completion of the 12-month follow-up. If necessary they were also offered sessions by AI during the follow-up period. The number of sessions were registered and described in Paper 1. AI being the principal investigator could represent an ethical problem as he had a central function both in enrollment and diagnostic procedures, conducted all phases of the study including management of follow-up visits, and provided extra sessions when needed. The multiple roles represent an ethical problem as patients might have felt a pressure against declining participation. To minimize this problem, patients were reminded that they could withdraw from the study whenever they wanted, and that this would not have any negative consequences for their follow-up and chances to get additional psychiatric help.

### **2.6.2 Ethics and study approval for Study 2**

The study was approved by the Regional committee for medical and health research ethics (REK) Region south at February 15th 2006 (REK ref. no: S-06019), and by the Norwegian social science data services at January 4<sup>th</sup> 2006. All patients received verbal and written information, and signed a formal consent to participate in the study. The study was registered in the ClinicalTrials.gov with the number NCT00932919 in 2006, but by a mistake it was not registered as received until July 3<sup>rd</sup> 2009. Documents confirming that this was a non-intended mistake exist.

If needed, the study participants were offered further help or referral to another therapist after completion of the 12-month follow-up. We asked all patients about side effects of the therapy at the 12-month follow-up.

The fact that AI not only conducted the study, but enrolled the patients and did the diagnostic interviews could represent an ethical problem, as it could make it difficult for the patients to decline the invitation to participate. To counteract this, all patients were informed verbally before the first session about the study and about the possibility to decline participation at any time, as also stated in the written information. The principal investigator of the study (AI) did not conduct the therapy in this study. Among the 136 patients excluded from the study, thirteen patients declined study participation. They were not obliged to give a reason for declining acceptance, but some stated spontaneously that they did not want to be videotaped during the interviews with MINI PLUS, SCID II and ADIS, which was a necessary requirement for study participation. All patients who declined to participate in the study were offered referral to another treatment option relevant to their condition.

For ethical reasons, moderate to high risk of suicide as measured by the MINI PLUS interview was one of the exclusion criteria. None of the patients needed extra interventions because of suicidal intentions during treatment or follow up.

## **3 Results**

### **3.2 Summary of results from the papers**

#### **3.2.1 Paper 1**

Patients having received TFT treatment reported larger improvements than those on the wait-list condition on all 6 scales. On the mean score (*GSI*) of the

SCL-90-R, the anxiety subscale of the HAD and the subscale on social life and leisure activities of the Sheehan's disability scale the differences were statistically significant ( $p < 0.01$  for all), with effect sizes ranging from 0.89 to 1.13.

After the 2 ½ months waiting period, patients on the wait-list received similar TFT treatment. All patients ( $n=45$ ) were assessed 1-2 weeks post-treatment, and at three and 12 months post-treatment. Compared to pretreatment values the scores on all 6 measures were significantly changed at 12-month follow-up, four with  $p < 0.001$ , and two with  $p < 0.01$ . Effect sizes ranged from 0.44 to 0.97. The main changes occurred pre-post treatment, and patients kept their gains at 3- and 12-month follow-up for all six outcome measures.

### 3.2.2 Paper 2

Patients that received active treatment did significantly better ( $p < 0.05$ ) pre-post treatment than the wait-list patients on all assessments except for the BSQ, for which the  $p$ -values for wait-list vs both CT and TFT were 0.05. There were no significant differences between patients receiving CT ( $n=24$ ) or TFT ( $n=24$ ) although there was a trend towards better outcome for the CT condition on all measures.

After the three months waiting period, the 24 patients on the wait-list were randomized to five sessions of TFT ( $n=12$ ) or 12 sessions of CT ( $n=12$ ). All the 36 patients who had received TFT were then compared to the 36 patients who had received CT. For the two primary outcome measures on agoraphobic avoidance and anxiety we did not find significant differences between CT and TFT. For the primary outcome measure on agoraphobic avoidance we also performed analyses of covariance (ANCOVAs). This showed a non-significant difference of 0.31 (95% CI -0.93 to 0.32),  $p=0.33$  in favor of CT post-treatment, and a non-significant difference of 0.041 (95% CI -0.63 to 0.72),  $p=0.90$  in favor of TFT at the 12-month follow-up.

Repeated measures ANOVAs showed a trend of better results for CT than for TFT also at the 12-month follow-up on all outcome variables except for the ADIS scores of anxiety and avoidance, although none of the differences were statistically significant. The TFT condition demonstrated medium effect sizes pretreatment to 12-month follow-up (Cohen's  $d$  0.5-0.8) on five measures (BDI, BAI, ACQ frequency and belief, BSQ), and large effect sizes ( $d > 0.8$ ) on five



variables (MI and the ADIS anxiety, avoidance, inference and distress). The effect sizes of the primary outcome variables are shown in Table 4. The CT condition demonstrated a medium effect size on one parameter (BDI), and large effect sizes on the other 9 variables. At the 12-month follow-up, 18 (50%) of the CT patients and 10 (28%) of the TFT patients no longer met the diagnostic criteria for agoraphobia ( $p=0.09$ ). On the employment status changes were small.

The analyses were performed as intention to treat (ITT), applying last observation carried forward (LOCF) for missing values. In addition, as recommended by Sterne et al (Sterne et al., 2009), we have analyzed the primary effect variables for the 69 completers (CT=34, TFT=35). This per protocol analysis showed only small differences from the ITT analyses, which means that losing three patients to follow-up had little influence on the results:

Table 4 Effect sizes (Cohen’s *d*) for analyses on the primary effect variables of *completers* pre-post treatment, and pretreatment to 12-month follow-up. Results for ITT analyses are given in parentheses.

Avoidance	Pre-post treatment	Pretreatment to 12-month follow-up
CT, n=34 (36)	1.43 (1.33)	0.96 (0.92)
TFT, n=35 (36)	1.09 (1.06)	1.11 (1.10)
Anxiety	Pre-post treatment	Pretreatment to 12-month follow-up
CT, n=34 (36)	1.41 (1.32)	0.98 (0.93)
TFT, n=35 (36)	1.05 (1.03)	1.08 (1.06)

### 3.2.3 Paper 3

We found that both being single and having a depressive disorder at baseline were significantly associated with less improvement for the sample as a whole. The negative effect of being single vs married/cohabitant was significantly larger for CBT than for TFT pre-post treatment, but not pretreatment to 12-month follow-up. The negative effect of having a depressive disorder at baseline was significantly larger for TFT than for CBT pre-post treatment, but not for pretreatment to 12-month follow-up. Age of onset and duration of

illness did not predict or moderate treatment outcome, hence we could not confirm the findings by others of these two variables being moderators.

## **4 Discussion**

### **4.1 Summary of the main findings**

Patients with various anxiety disorders had statistically better outcomes after TFT treatment compared to those on a wait-list condition on the three variables *GSI* from SCL 90-R, the HAD anxiety scale and the social life and leisure activities scale from the SDS ( $p < 0.01$ ). The change in scores from pretreatment to 12-month follow-up were statistically significant on all outcome variables for the sample as a whole, the effect sizes ranged from 0.44 for depression (HAD) to 0.97 for social life and leisure activities (SDS).

Both CT and TFT were significantly more effective than a wait-list condition in the treatment of agoraphobia ( $p < 0.001$ ). The differences between CT and TFT were not statistically significant neither from pretreatment to post-treatment nor from pretreatment to 12-month follow-up, but there was a trend ( $p$  ranging from 0.06 for ADIS inference to 1.0 for BSQ) towards better effects following CT on all measures except for the avoidance and anxiety scores from ADIS pretreatment to 12-month follow-up.

Being married/cohabitant was significantly associated with better treatment outcomes for the sample as a whole, the positive effect upon outcome was more pronounced for CBT than for TFT pre-post treatment. Comorbid current depressive disorder was significantly negatively associated with treatment outcome for the sample as a whole, but more for TFT than for CBT pre-post treatment. Age of onset and duration of illness did not predict or moderate treatment outcome.

### **4.2 Discussion of the main findings**

#### **4.2.1 Discussion of the results of Study 1 compared to the findings of others**

Four clinical studies have compared TFT (Connolly & Sakai, 2011; Schoninger & Hartung, 2010) or EFT (Church et al., 2013; Church, Pina, Reategui, & Brooks, 2012) to a wait-list condition, as we did. Only the study by Schoninger and Hartung was on anxiety, the other three were on PTSD. Because there is a

limited number of studies on TFT, we find it reasonable to discuss our findings also in relation to those of EFT even if conducted in samples with different conditions/disorders.

Schoninger and Hartung reported an effect size of 1.52 for TFT pre-post treatment for public speaking anxiety and no improvement for the patients on the wait-list condition (described as delayed treatment in their study), and an effect size of 1.66 pre-post TFT treatment for the group treated after a four weeks waiting period. The three other studies did not report effect sizes. We found an effect size of  $d=0.94$  for the reduction in our primary outcome variable (*GSI*) for TFT patients pretreatment to 2 ½ month follow up compared to the wait-list patients.

There were no significant changes in our study on post-treatment to 12-month follow up scores, so the positive effects of TFT were maintained. Our results are largely in line with those of Connolly and Sakai, who did a two-year follow-up of PTSD symptoms and found a continued decrease in symptoms on most measures from posttest to follow-up (Connolly & Sakai, 2011). Our results are also in accordance with those of the Church et al study on EFT for veterans, in which they found that the positive treatment effects were sustained at follow-up assessments at three and six months (Church et al., 2013). Schoninger and Hartung conducted a follow-up with 31 of the 48 patients five months after treatment. Among the participants 28 reported less apprehension in public speaking situations, but no assessments were performed.

Of these four studies, only the study of Schoninger and Hartung applied TFT for patients with anxiety problems, as in our first study. However, their sample most likely was not representative of a clinical population and did probably have less distress than our patients, who had a mean score of 1.6 on the *GSI* indicating that our sample was a clinical population with significant distress. This may explain our findings of lower effect size because we treated a supposedly more distressed sample.

#### **4.2.2 Discussion of the results of Study 2 compared to the findings of others**

Five other clinical studies on TFT or EFT have used an active treatment condition as comparator, as in our Study 2. Of these, one was a study on TFT for acrophobia (Carbonell, 1997), two studied EFT for anxiety disorders (Baker & Siegel, 2010; S. Wells et al., 2003), one is a study on EFT for OCD (Moritz et

al., 2011) and one on EFT for PTSD (Karatzias et al., 2011). In our study we found effect sizes of 1.10 for TFT and 0.92 for CT on the primary effect variable of avoidance from pretreatment to 12-month follow-up. This is lower than the results pre-post treatment in the studies by Wells et al and Baker and Segal, in line with the results found by Karatzias et al, and higher than found by Baker and Segal at follow-up. The study by Karatzias et al compared EFT to EMDR, and concluded that their results indicate lack of superiority of any of the two treatment conditions over the other.

The study by Carbonell on acrophobia (Carbonell, 1997) did not report effect sizes, and comparisons of results are therefore difficult. She found statistically significantly lower SUD scores when exposed to a height for those who had been treated with the specific algorithm for phobias than for those who had received a treatment with tapping on parts of the body that is not used in TFT. Also the study by Moritz et al did not report effect sizes, but as the scores on Y-BOCS did not significantly change for any of the interventions the effect sizes may be supposed to be low.

In conclusion there are no other studies on TFT for agoraphobia, but our results are comparable to studies on patients from other clinical samples with a supposedly comparable amount of stress as our patients.

#### **4.2.3 Discussion of the results from paper 3**

In contrast with three studies that reported that later age of onset predicts a better outcome (Chambless et al., 2017; Hendriks et al., 2012; Nakano et al., 2008), we found no correlations between treatment outcome and age of onset. This discrepancy may be because we included only patients with severe agoraphobia. Unlike the findings of Chambless et al (2017), we did not identify a moderator effect of age of onset. This difference may be due to Chambless et al applying another treatment modality than TFT as the comparator to CBT.

We found no predictive or moderator effect of duration of symptoms on treatment outcome. This is in contrast with Hendricks et al who found that a shorter duration of illness predicted a better outcome for CBT than for the antidepressant medicine paroxetine. The discrepancy may be due to their sample being aged 60 years and older while we included patients from the age of 18, and that medication with SSRI is very different to TFT as a comparator to CBT.

In line with Hoffart et al (Hoffart, Økstedalen, Svanøe, Hedley, & Sexton, 2015) we found that being married/cohabitant was a positive predictor of treatment outcome for the whole sample. In line with Porter and Chambless (Porter & Chambless, 2015), but in contrast to Hoffart et al, we found current depression at baseline to be unrelated to treatment outcome from CBT. Our study is the first to show that current depression and being married/cohabitant may be moderators of treatment outcome of CBT relative to other treatments of agoraphobia.

### **4.3 Methodological discussion**

#### **4.3.1 Discussion of patient samples**

##### *Sample 1*

The first study included patients with agoraphobia, social phobia or PTSD, or a combination of these, so one limitation is that the sample was heterogeneous regarding type of disorder. On the other hand, this diversity of anxiety conditions makes the study more clinically valid, as it resembles the situation in ordinary clinical practice. This is strengthened by the only exclusion criterion being on-going psychosis. As there were no statistically significant differences between the non-participants and the included patients on sociodemographic data, the study may be assessed as having good internal validity.

An overview of epidemiological studies of anxiety disorders found that specific and social phobias often start in childhood or early adolescence, while GAD, panic disorder and agoraphobia typically develop during late adolescence and early adulthood (Michael, Zetsche, & Margraf, 2007). In our study most patients had social phobia or agoraphobia, and so the mean age of onset of 19 years that we found is similar to the findings of Michael et al. In our study 73% of the patients were women, which corresponds with the estimate by Michael et al that women have a higher prevalence of anxiety disorders. Our finding of a long duration of symptoms corresponds well to the description by Kessler et al suggesting that anxiety disorders are often persistent throughout the entire life course (Kessler, Ruscio, Shear, & Wittchen, 2009). Also our finding of high occurrence of comorbidity both with other anxiety disorders and other axis I disorders corresponds to the findings of meta-studies (Kessler et al., 2005; Michael et al., 2007). Based on these comparisons we suggest that our study has satisfactory external validity.

Our failure to assess inter-rater reliability for the diagnostic procedure may be considered a limitation. To some extent this was accounted for by the evaluator (AI) having extensive experience with the MINI, that it has been used in other studies in this field (Meulenbeek et al., 2010), and that other studies have reported a good test-retest agreement (Mordal et al., 2010).

Failing to exclude patients with on-going dependence of alcohol and drugs may be a limitation, but as there were only 6 patients with one such diagnosis in our study we believe that this does not represent a major problem. Almost half of the patients had one or more comorbid personality disorders. This may have affected results, but as there were twice as many with a personality disorder in the TFT group than in the wait-list group, this probably favors the conservative hypothesis.

The fact that many patients used psychotropic drugs, as well as some patients getting additional sessions with another therapist during follow-up, limits our results. These allowances were made to secure the inclusion of enough patients. However, we found that receiving additional sessions was negatively correlated to treatment outcome.

### *Sample 2*

We included patients with agoraphobia with or without a diagnosis of panic disorder as their primary disorder. The MINI PLUS only has a few items on the diagnosis of agoraphobia, but these items appearing immediately after the part on panic disorder helps in the diagnostic decision (D. V. Sheehan et al., 1998). As there were no difference between the CT and TFT patients in proportion of who was self-referred, and there were no correlations between type of recruitment and treatment outcome, it is likely that the type of recruitment did not affect differences in the results for CT and TFT.

As we found no significant differences between the excluded and included patients with respect to age and gender, we do not have reason to believe that there were systematic differences other than those related to inclusion and exclusion criteria between the included and excluded patients. However, we do not know if there were differences in other characteristics (symptom intensity, comorbidity) that may have affected the treatment outcomes.

As in Study 1, it is a limitation that many patients used psychotropic drugs, nine even raising their dosage. The reason for these allowances was the

same as in Study 1, i.e. to be able to include enough patients. Including in statistical analyses patients that reported at follow-up that they had raised their dosage of psychotropic medicine is questionable, but can partly be justified by the finding of only small differences in the primary effect variables when performing statistics on the remaining 63 patients.

Allowing psychotropic medication and other types of additional treatment in both studies reduces the possibility to draw firm conclusions from our findings. In their systematic review from 2015, Porter and Chambless report that *“most studies did not restrict patients from seeking additional treatment during the follow-up period”* (Porter & Chambless, 2015). Although these allowances make our conclusions weaker, they contribute to a better external validity, as changes of medicines and dosage are common in ordinary clinical practice (Insel & Wang, 2009).

Our samples comprised more females than males having agoraphobia and is in accordance with both a meta-study from Canada (Somers, Goldner, Waraich, & Hsu, 2006) and a Norwegian sample (Hoffart et al., 2015). Both Hoffart et al and an Australian study (Malbos, Rapee, & Kavakli, 2013) found age of onset of agoraphobia to be in the mid-twenties, as we found in our study. The duration of symptoms in our study was similar to the study by Hoffart et al, but somewhat shorter than found by Malbos et al. Also our findings of axis 1 comorbidity is similar to the findings of Hoffart et al and Malbos et al, and to a study by Kessler et al (Kessler et al., 2005), but we found lower comorbidity with avoidant personality disorder than did Hoffart et al.

#### **4.3.2 Discussion of research design**

Both Study 1 and 2 were randomized control trials (RCTs), and in both studies a wait-list condition was a comparator. Both studies had assessments before and after the interventions, and at follow-up. It has been argued that RCTs are of limited value in the field of complementary and alternative medicine research (Carter, 2003). In RCT studies the subject of interest are only one or a few components of the therapy, and so the studies do not encompass the holistic approach that is seen as a main part of complementary and alternative (CAM) treatments (Verhoef et al., 2005). Since TFT does not seem to rely on other factors than the questioning and tapping (Callahan & Trubo, 2001), and therefore does not stand out as being a typically holistic form of therapy, we

consider RCTs to be just as valid for examining the possible effects of TFT as they are for conventional therapies.

### *Study 1*

In the first study a wait-list condition was the sole comparator. The purpose of applying wait-list was to control for the passage of time and the possibility of spontaneous remission (Posternak & Miller, 2001). A wait-list condition does not fully account for effects that might be produced by a placebo condition, as the relation with a therapist, hope and positive expectations, and the wish to please the therapist (Finniss, Kaptchuk, Miller, & Benedetti, 2010). Arrindell et al found a trend towards reduction in psychopathology when groups of psychiatric patients were assessed on two occasions with no therapeutic interventions in between (Arrindell, 2001). We found similar results in Study 1, but not in Study 2.

In a special issue on the placebo concept in psychotherapy, Herbert and Gaudiano wrote that this concept in psychotherapy research gives rise to both conceptual and practical problems, and argue against using placebo in studies on the effect of psychotherapy (Herbert & Gaudiano, 2005). They make a possible exception for TFT, and suggest that the tapping can be done on points that do not fit in with the prescribed sequences. In their article they specifically raise the question of which psychological factors are to be labeled psychotherapeutic, and which should be called placebo. If therapists are told to treat patients with incorrect tapping points and sequences, they will most certainly communicate other nonverbal signals to the patients than when knowing that they perform the correct procedure (Luborsky et al., 1999). And it might be practically impossible to ascertain that neither patients nor study therapists search the internet to check if they get or give the correct version of TFT. Therefore we will argue that also for TFT the use of a sham treatment as comparator would not be a true placebo condition.

The TFT therapist in the first study was the foremost Norwegian proponent for TFT. At the time of planning and performing this study, the study investigator (AI) had a clear allegiance to this therapy method, having observed several good therapeutic results from applying it with patients with different diagnoses. So it is correct to state that this study might be vulnerable to a considerable amount of allegiance effect (Luborsky et al., 1999).



Only offering two sessions of TFT to each patient was not optimal, as the recommended number of sessions for TFT was five sessions (Holmaas, 2017; Uldal, 2007). Since some previous studies showed that only one or a few treatment sessions could be sufficient (Folkes, 2002; Salas, 2001), we found it justifiable to offer only two sessions, as further sessions were beyond the resources for our study. A main limitation to Study 1 is that the randomization key was known to the principal investigator (AI), but as the patients were enrolled consecutively, this would not be a source of bias.

### *Study 2*

To overcome the problems of lacking a comparator or placebo condition in Study 1, we included CT as comparator to TFT in the second study, as we acknowledged CT to be one of the recommended treatments for agoraphobia (Norton & Price, 2007; Pilling, Whittington, Taylor, & Kendrick, 2011). To control for the effect of passing of time we included a wait-list condition also in Study 2.

To make the study as clinically valid as possible, we offered five sessions of TFT, which was the recommended number of sessions by the leading therapist in Norway at the time of the study (Uldal, 2007). As we wanted to make the CT comparator condition as similar as possible to what was recommended, we followed the prescribed structure from David M. Clark and Paul M. Salkovskis (Hawton et al., 1989), and offered 12 sessions of CT. Thus it is possible that the increased time of treatment and therapist contact for the CT patients may have biased our results, probably in favor of the CT condition.

Avoiding problems with allegiance was a major concern in Study 2. By the time it was planned and performed, AI had taken a two-year course in CBT, and had stopped applying TFT in daily clinical practice. The TFT therapist Anne Trine Eia, who treated half the patients in the study, was certified as a TFT therapist, but was not a pivotal person in the TFT milieu in Norway. The two CT therapists had a two-year seminar in CBT some years before the study, and were dedicated in applying CBT as their primary psychotherapeutic method. Their supervisors were well-known CBT therapists and researchers. The therapeutic milieu in which the study was performed was and still is a traditional psychiatric fellowship, with allegiances to biological psychiatry supplied with psychodynamic and cognitive psychotherapeutic traditions. The blinded evaluators worked in the same environment. So if any allegiance was present, it

would have been towards CT and not TFT. In all, we conclude that the research design for study 2 was methodologically sound.

#### **4.3.3 Discussion of assessments**

Recently the Hospital anxiety and depression (HAD) scale has been questioned as a mean to differentiate between anxiety and depression (Cosco, Doyle, Ward, & McGee, 2012), and there is an ongoing discussion whether it should be applied for screening and assessment (Coyne & van Sonderen, 2012). Our intention when applying HAD in Study 1 was to measure changes in symptoms of anxiety and depression, and not for screening or establishing diagnoses. Our findings of differences in beneficial effects between the anxiety and depression subscales from before treatment to the 12-month follow-up, with *F* scores of 20.1 for anxiety and 4.46 for depression, indicate that HAD may discriminate between anxiety and depression when measuring change. We have not found that the use of HAD as a measure of symptom changes has been questioned.

Unfortunately, among the self-report questionnaires in Study 1 we were not able to calculate the Cronbach's alpha from HAD and SDS. For the other self-report questionnaires we found acceptable values for Cronbach's alpha ranging from 0.87 (ACQ frequency) to 0.97 (MIAAL).

In both studies we did not estimate inter-rater reliability of the diagnostic assessments. This was partly compensated for in Study 2 by 10 randomly chosen videos of a MINI PLUS interview and 10 of a SCID II interview being re-scored by one of the co-authors (TD) without her knowing the scores by AI. The re-score showed full agreement as to the primary diagnosis of agoraphobia with or without a history of panic disorder. In addition all patients were given a diagnosis of agoraphobia by a clinician applying the ADIS interview, and the diagnosis of agoraphobia is also strengthened by the inclusion criterion of  $\geq 2.5$  in MIAAL securing a specificity of 1.0.

#### **4.3.4 Statistical considerations**

Using the principle of last observation carried forward (LOCF) in both studies may be discussed as the use of LOCF may introduce bias in the results (Altman, 2009; P. Lane, 2008). Besides, we did not use the principle of intention to treat analysis completely in Study 1, as 8 patients in this study were omitted from the analysis.

There were no statistically significant differences between the 7 omitted patients that we have data for and the 45 included patients on the demographic data described in Table 2. Only three of the included 45 patients had a substantial loss of data due to drop-out. One did not return after the first TFT treatment, another did not complete rating scales at the three- and 12-month follow-up. One patient in the wait-list group did not provide data at the 12-month follow-up. The fact that two of the three patients with missing data were in the group who received TFT first, most probably favors the conservative hypothesis of TFT not being better than wait-list (P. Lane, 2008). We therefore consider that the use of LOCF in Study 1 was justified, both due to the reasons for omission, and due to the small number of missing values among the remaining 45 patients.

In Study 2 we also used the principle of LOCF. There were only three drop-outs among the 72 participants (4.2%). One of the drop-outs was on the wait-list condition and showed up for assessment after the waiting period, which means that only 3.6% of the scores on the primary effect variables were lacking. In addition there were some incidental missing values among the secondary effect variables due to forgetfulness, but these may be assumed to be unrelated to the observations and therefore can be considered as random error and a minor problem (P. Lane, 2008). We therefore feel justified in applying LOCF also in Study 2.

As there were no previous studies on TFT or EFT for agoraphobia, our assumption of 85 % effectiveness for TFT was no more than a qualified guess. As also the delta limit for testing non-inferiority was highly uncertain, we found it warranted to switch the presentation of our findings from a non-inferiority to a superiority trial as done by others (Helgesen et al., 2015).

#### **4.4 Adverse effects during and following treatment**

It should be a broadly accepted fact that a therapy that can be helpful to patients also can be harmful, as highlighted by Berk and Parker (Berk & Parker, 2009). I once experienced an example of a serious adverse event applying Traumatic incident reduction (TIR) for a patient, in that she suddenly remembered a traumatic event she had long forgotten, and that remembering it led to serious suicidal thoughts. Berk and Parker described a tacit assumption among therapists that psychotherapy is largely without risks. In addition to this being a faulty assumption, we find that it may also be

harmful and even dangerous, as it may lead to a lack of awareness of risks due to the therapy itself.

As described by Linden there are several difficulties in recognizing and studying side effects in psychotherapy, as there is a tendency among therapists not to recognize or admit adverse events, problems with the differentiation between side effects and unavoidable negative effects during therapy, and a lack of procedural standards (Linden, 2013). He stated that it is a serious problem that adverse events monitoring is not mandatory in psychotherapy trials and that there is a lack of consensus on definitions and classification of side effects.

Church and Feinstein reported that having examined the studies on TFT and EFT in which adverse events had been discussed no adverse effects were found, and related that to the affect-reducing properties of these therapies (Church & Feinstein, 2013).

We wanted to explore if the therapy led to adverse effects, and asked patients in Study 2 two open questions at the 12-month follow-up for side effects of the treatment and if they had negative experiences from participating in the research project. Seven patients (10%) reported adverse effects (CT=6, TFT=1,  $p=0.06$ ). Among the 6 CT patients reporting side effects, three reported a worsening of symptoms, and the other three that the treatment was more unpleasant or tiresome than expected. One TFT patient told about re-experiencing traumatic memories that were not successfully treated during the five TFT sessions. The patient still had such memories after the end of treatment, and received additional treatment immediately after the last follow-up.

On the question of negative experiences of participating in the study, one TFT patient was disappointed at receiving only five sessions. The patient showed among the highest agoraphobia symptom scores initially, and experienced a symptom reduction of approximately 50% symptom post-treatment. After the last follow-up, she received additional sessions of TFT.

We conclude that both from TFT and CT patients may experience adverse effects, but that none of the adverse effects in Study 2 were serious. Due to the small number we will draw no conclusions from the difference between CT and TFT.

#### **4.5 Treatment rationale and potential mechanisms for TFT**

A challenge with TFT is the lack of a scientific rationale for how this therapeutic method may have possible beneficial effects. Callahan wrote about his core concept “Thought field” that it is a non-observable structure in the mind containing information, for the clinical use he concentrated on the Thought field producing psychological distress. He did not agree with theories connecting such structures to specific parts of the brain as the amygdala, which he called a “hardwiring” theory, but rather described the Thought field as software. He explained the mental problems as perturbations in the Thought field, and described that TFT exerts its effect by collapsing the energy in such perturbations and thereby eliminating them. Callahan referred to Eastern tradition of energy meridians for his theory of energy flow in the body, and stated that every perturbation in the thought field is associated with a specific meridian (Callahan & Trubo, 2001).

In contrast to Callahan’s theory, Andrade and Feinstein emphasized that the stimulation of mechanoreceptors may lead to disrupt anxiety patterns in the amygdala and other brain structures linked to emotional problems (Andrade & Feinstein, 2004). The theory of how brain structures and processes may be influenced by the tapping procedure in TFT and EFT has been further elaborated by Feinstein (Feinstein, 2010) and Church and Feinstein (Church & Feinstein, 2013; Feinstein & Church, 2010), and is supported by findings of Hui et al who presented preliminary results indicating that acupuncture may influence activity in parts of the brain (Hui et al., 2000; Hui et al., 2005). This view is also supported by findings of Diepold and Goldstein who presented a case study showing persistent changes in brain wave patterns following 20 minutes of TFT, corresponding to a beneficial clinical effect, involving a reflection in brain activity of the thought field as described by Callahan (Diepold & Goldstein, 2009). In addition, Church et al found a decrease in cortisol level 30 minutes after an hour long session with EFT in a non-clinical sample, with a parallel reduction in psychological distress indicating that the effect of EFT may in some way be mediated by cortisol regulation (Church, Yount, & Brooks, 2012).

In a paper reporting a study of the efficacy of a form of treatment for PTSD called Numerical distraction therapy (NDT); Isaacs suggested that dual attention might be an underlying mechanism of change common to EMDR, TFT

and NDT (Isaacs, 2004). The basic instruction in EMDR and TFT is that the patient shall have in mind a distressing thought while at the same time performing a bodily procedure of tapping (TFT) or following a finger being moved back and forth or other alternating left/right stimuli (EMDR) (Shapiro, 1995). In NDT the procedure is counting and therefore largely mental, but in addition it has a sensory part in saying the numbers out loud and thereby hearing them. Isaac referred to a speculation by Shapiro that the EMDR's success might primarily stem from patients focusing on two different stimuli simultaneously (Shapiro, 1995, 2001), made assumptions in line with Andrade, Feinstein and Church about amygdala inhibition, and posed a theory that overload of working memory causes it to malfunction, and creates beneficial changes in the memory of the distressing event that is the target of treatment.

Based on clinical experience we have speculated that in some way the dual attention in TFT and EMDR may be an important factor in conveying the positive changes observed in patients during these treatments as suggested by Isaacs. In addition, when TFT has been carried out successfully, the treatment seemingly has included a component of relaxation for most patients. Some patients even yawned and reported being sleepy, when the symptom reduction made by TFT began. Therefore we may speculate that when patients can be calm while thinking of troublesome feelings or re-experiencing terrible memories, they may realize that these feelings or memories are not dangerous per se. This may find support in a theoretical paper by Lane in which he links the effects of TFT and EFT to the concept of counterconditioning of anxiety (Wolpe, 1990), caused by changes in neurochemistry (opioids, serotonin, gamma-amino-butyric acid and cortisol) (J. R. Lane, 2009).

We may further speculate that this calmness is as much a bodily experience as it is a mental insight, and that this may be the reason for the effect that some patients experience from only one session of TFT. This resembles the effect of a well-designed behavioral experiment, as described in the *Oxford guide to behavioural experiments in cognitive therapy* (Bennett-Levy et al., 2004). Such behavioral experiments were a central part of the CT treatment in Study 2 (Hawton et al., 1989), so we may hypothesize that CT and TFT can be different ways of targeting factors of change that have important components in common. Maybe the turning point in every beneficial therapy for anxiety symptoms is when patients experience that they can think of the

distressing event without a substantial sense of discomfort, whether this change comes from bodily procedures as in TFT, EFT, NDT and EMDR, a redefinition of the meaning of the event as in CBT, calming of bodily symptoms as in treatment with psychotropic medicines or mindfulness, or experiencing that the anxiety symptoms are not dangerous and can be endured, as in behavioral therapy. Taking this a step further leads us towards the possibility that it is how we handle our psychological processes that for a large part determines which effects life events have on us (Kinderman, Schwannauer, Pontin, & Tai, 2013), which is a central part of Metacognitive therapy (A. Wells, 2009). Related to this is a hypothesis that reducing the fear of feeling fear contributes to improvement from panic disorder and agoraphobia, which is supported by a study by Smits et al (Smits, Powers, Cho, & Telch, 2004).

One main part of TFT is imaginal exposure, which is based on emotional processing theory (Foa & Kozak, 1986), as the patient is asked to focus on a situation in which their anxiety was overwhelming (Callahan & Trubo, 2001). The tapping and the presence of the TFT therapist may help the patient to feel secure in spite of the anxiety-provoking memories, thereby being able to stay in control. Probably the calmness of the therapist and the concrete procedure of tapping convey a belief that the reliving of the memory is both endurable and not dangerous and that the therapy will be helpful. As a consequence the patient may overcome his/her belief that anxiety must be suppressed, which in turn renders him/her less attentive to bodily sensations that formerly could start a panic attack. We think that our speculations from the observations of patients becoming calm during TFT may be partly connected to these derivatives from emotional processing theory.

#### **4.6 Criticism against TFT studies**

In the Editors introduction to a special series in the Journal of clinical psychology from 2001, Larry Beutler refers to criticism from several contributors to claims of presumed efficacy and effectiveness from TFT, and to Roger Callahan's responses to this criticism which led to Beutler inviting him to publish papers in a special edition without the usual peer review process (Beutler, 2001). The five papers reporting original research (Callahan, 2001a, 2001b; Johnson et al., 2001; Pignotti & Steinberg, 2001; C. Sakai et al., 2001) were sent to reviewers although they were guaranteed to be published. All the

reviewers indicated that they would recommend against publication of these five papers. Instead of the papers being refused, the reviews were published following the respective papers they reviewed (Herbert & Gaudiano, 2001; Kline, 2001; Lohr, 2001; McNally, 2001; Rosner, 2001). All reviewers pointed to serious methodological shortcomings in the papers they reviewed, and to the TFT researchers drawing conclusions on effectiveness that was not grounded in the study findings. Considering these criticisms Monica Pignotti retracted the paper by her and Mark Steinberg (Pignotti, 2005). Later she and Bruce Thyer criticized proponents of TFT (Feinstein, 2008) for underreporting criticism against TFT and omitting case reports not confirming effectiveness from TFT (Pignotti & Thyer, 2009).

In a paper from 2009, McCaslin criticized the study on small animal phobia from 2003 (S. Wells et al., 2003), concluding that it does not support the assertion by Feinstein (Feinstein, 2008) of EFT being an efficacious treatment for this phobia (McCaslin, 2009). In this paper he also referred to a study aimed at comparing EFT to placebo in the form of two different sham treatments (tapping non-meridian points on the body, or tapping on the same places on a doll as would have been tapped on the body, in both conditions following the EFT procedure aside from where to tap) for a non-clinical sample of 119 students with some form of anxiety symptoms (Waite & Holder, 2003). They found a positive trend of symptom decrease pre-post treatment for EFT ( $p=0.06$ ) and a significant decrease for the other two therapy conditions ( $p=0.008$  and  $p=0.003$ , respectively), but no decrease for the control group. Thus, their findings contrast those of Carbonell as previously described in chapter 1.3 (Carbonell, 1997). More recently, a systematic review on CAM treatments for PTSD symptoms stated that the scientific evidence for TFT and EFT is unclear or conflicting for such symptoms (Wahbeh, Senders, Neuendorf, & Cayton, 2014).

## **5 Conclusions**

The results from Study 1 suggested that TFT may have beneficial effect upon anxiety disorders, both immediately post treatment and three and 12 months post treatment.



The results from Study 2 indicated that TFT could be an alternative to CBT for patients with agoraphobia, but showed that CBT may have beneficial effects upon a broader spectrum of symptoms than TFT. Further, Study 2 identified being married/cohabitant and having a current depressive disorder as being positive and negative predictors of treatment outcome for agoraphobia.

## **6 Implications for clinical practice and further research**

### **6.1 Clinical practice**

TFT and EFT are applied by many therapists both with and without a health professional background (Robert Schwarz, personal communication, December 23, 2013), and these therapies are sought by many people. Study 1 fitted in with other studies on energy psychology therapies as it mostly covered TFT for psychiatric conditions not tested by others. Study 2 represented a leap forward, as it described the effects of TFT for one of the main anxiety diagnoses and with a serious symptomatology, and compared TFT to the best studied and best founded therapy for this condition.

The clinical value of the two studies is increased by their high external validity. They both had broad inclusion criteria; they were performed in ordinary outpatient work in a hospital far from a university, and the frames of the test therapy (TFT) in Study 2 were similar to that of the usual frames for this therapy at the time of the study. Besides, very few patients were excluded from Study 1, and in Study 2 few patients were excluded for other reasons than lack of the study diagnosis or a low degree of symptoms.

Our results indicate that TFT is effective for a clinical population with long duration of anxiety symptoms and a wide range of comorbid conditions. Partly based on results from Study 1 TFT has recently become registered in the National Registry of Evidence-based Programs and Practices (NREPP) (<http://nrepp.samhsa.gov/ProgramProfile.aspx?id=60#hide3>) conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), an agency within the U.S. Department of Health and Human services (<http://www.nrepp.samhsa.gov>).

Since he started with TFT in the late 1990s and up to 2016 Mats Uldal educated about 1500 TFT therapists in Norway and 500 in 9 other countries (personal communication June 8<sup>th</sup> 2016). Some of these are health care

professionals and apply TFT in their clinical work (Dyregrov, 2009), but most of the TFT practitioners are lay people. There are many potential problems in offering psychiatric treatment, both for health care professionals and others. There is an imbalance of power in the relationship between therapist and patient, and there is a risk of eliciting symptoms and memories that can lead to suicidal thoughts that go unnoticed by the therapist. For TFT to have a future place as an alternative to school medicine, it is necessary to establish support and supervision systems among the TFT therapists. It is important to underscore that both TFT therapists in our studies had an extensive background in teaching and in TFT, especially Mats Uldal, and that Anne Trine Eia got supervision from AI both before and during the second study. In addition, all study patients had a thorough evaluation and underwent systematic diagnostic procedures before entering therapy. Hence, our results are limited to highly qualified TFT therapists and a comprehensive clinical psychiatric evaluation before treatment, and cannot be generalized to other therapeutic context.

There are still too few studies to document the efficacy of TFT, and not enough positive results to recommend that TFT should replace CBT or any other well documented psychotherapy when the latter is available. But as there may be lack of qualified CBT and other therapists, and TFT can be easily learned, our Study 2 indicates that TFT may defend its position as a technique to try for patients with agoraphobia. If both CBT and TFT are available for a patient in need of treatment for agoraphobia, one should always choose CBT before TFT, especially if the patient has a concurrent depressive disorder. An exception to this rule in Norway may be therapeutic settings where TFT has been applied for a long time by experienced clinicians, as the Center for Crisis Psychology in Bergen <https://www.krisepsyk.no/in-english/about-us/> (Dyregrov, 2009).

Most alternative and complementary treatments are not officially regulated in Norway (Wiesener, Salamonsen, & Fønnebø, 2018). In line with these authors we will argue that a regulation will strengthen patient safety. Such a regulation should comprise both the education of TFT therapists and frameworks regarding how TFT should be executed.

One particularly positive feature of TFT is that it is easily taught to the person in need of help, so that he or she can use it by him/herself without

depending on a therapist. Our studies have not tested if TFT might be an acceptable alternative in parts of the World where evidence based therapies are rarely available, but we find it reasonable to support further trials under such circumstances building on former studies (Connolly & Sakai, 2011; C. E. Sakai, Connolly, & Oas, 2010; Stone, Leyden, & Fellows, 2009).

## **6.2 Suggestions for future research**

As there is a lack of knowledge about clinical effects of TFT and how this therapy might work, further research based on this thesis may be:

1. Basic studies of TFT applying Functional magnetic resonance imaging (fMRI) and other methods to test if TFT exerts the same kinds of biological effects as those found with other therapies for psychiatric disorders.
2. Dismantling studies if feasible, to explore if different parts of TFT are more important than others.
3. Studies with a sufficient number of patients and clinically meaningful delta margins to explore if TFT is non-inferior to CBT for agoraphobia.
4. RCT studies on the efficacy of TFT for anxiety disorders other than agoraphobia, as social phobia and generalized anxiety disorder as well as hypochondriasis and OCD, all compared to well-established psychotherapies.
5. Rigorous RCTs on the efficacy of TFT and EFT for patients with PTSD preferably carried out in clinical settings neutral to type of experimental and comparative types of therapy, to minimize the allegiance effect.
6. When more efficacy studies have been performed, a next step would be to do effectiveness studies both in ordinary outpatient clinics and in the CAM practices outside hospitals.
7. RCTs where TFT is compared to treatments with well documented effects for other conditions where TFT has shown beneficial effects in case reports and other not so rigorous studies as a RCT, both psychiatric conditions and other conditions such as chronic pain, smoking and alcohol cessation and dyslexia.
8. RCTs in circumstances where there is a great need for acute psychiatric help and few means for such help, as in refugee camps or areas that have recently lived through war or other huge catastrophic periods,

applying what is possible to achieve of solid scientific frames under the circumstances.

## 7 References

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