UiT
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Faculty of Health Sciences
Department of Psychology

Internet-based cognitive behavioural therapy

A novel approach to treating depression in primary care patients

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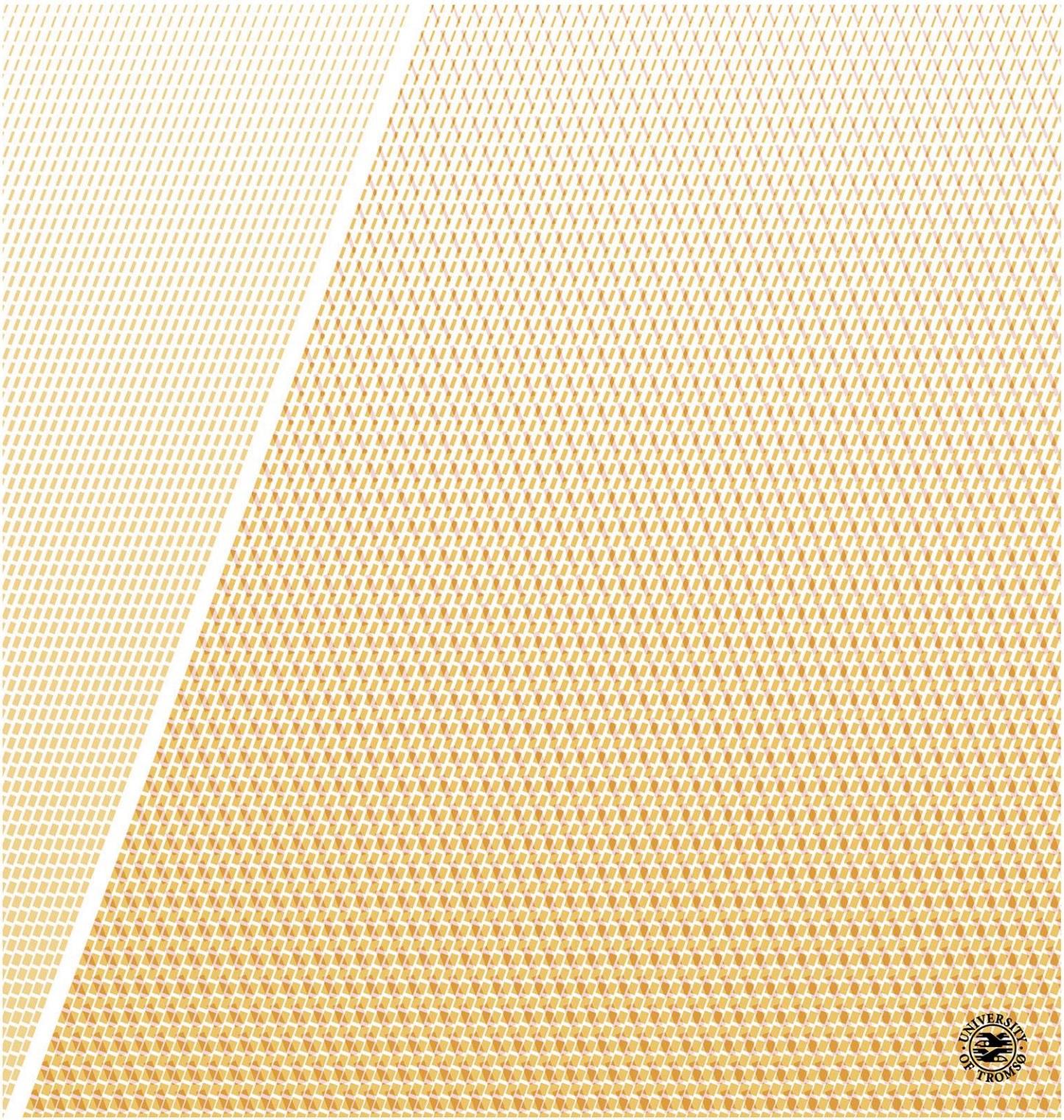
Ragnhild Sørensen Høifødt

A dissertation for the degree of Philosophiae Doctor – February 2015



INTERNET-BASED COGNITIVE BEHAVIOURAL THERAPY

A novel approach to treating depression in primary care patients

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Table of Contents

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List of Papers

Paper I

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Paper II

Høifødt, R.S., Lillevoll, K.R., Griffiths, K.M., Wilsgaard, T., Eisemann, M., Waterloo, K., & Kolstrup, N. (2013). The clinical effectiveness of Web-based cognitive behavioral therapy with face-to-face therapist support for depressed primary care patients: Randomized controlled trial. *Journal of Medical Internet Research, 15*(8), e153. doi: 10.2196/jmir.2714

Paper III

Høifødt, R.S., Mittner, M., Lillevoll, K.R., Katla, S.K., Kolstrup, N., Eisemann, M., Friborg, O., Waterloo, K. (2015). Predictors of response to Web-based cognitive behavioral therapy with face-to-face therapist support for depression: A Bayesian analysis. *Journal of Medical Internet Research* (submitted). doi:10.2196/jmir.4351

Paper IV

Wilhelmsen, M., Høifødt, R.S., Kolstrup, N., Waterloo, K., Eisemann, M., Chenhall, R., & Risør, M.B. (2014). Norwegian general practitioners' perspectives on implementation of a guided Web-based cognitive behavioral therapy for depression: A qualitative study. *Journal of Medical Internet Research, 16*(9), e208. doi: 10.2196/jmir.3556

Sammendrag

Målet med studiene i denne avhandlingen var å evaluere effekten av en behandling bestående av et internettbasert selvhjelpsprogram (MoodGYM) kombinert med korte samtaler med en terapeut. Vi ønsket også å undersøke om dette er en behandlingsmodell som pasienter opplever som nyttig og positiv.

Depresjon er en av de vanligst forekommende psykiske lidelsene, og for dem som rammes fører depresjon til både lidelse og vansker med å fungere i hverdagen. Mange av de som opplever milde til moderate depresjonsplager vil motta det meste eller all behandling i primærhelsetjenesten. Strukturert psykologisk behandling er mangelvare i allmennpraksis; til tross for at det finnes mange virksomme psykologiske behandlingsmetoder for depresjon og at pasienter ofte foretrekker slik behandling framfor medisiner. I tillegg anbefaler retningslinjer for depresjonsbehandling psykososiale intervensjoner som førstevalg av behandling for denne gruppen. De siste tiårene har det blitt utviklet en rekke internettbaserte intervensjoner som bygger på kognitiv atferdsterapi (CBT). Studier viser god effekt av slike intervensjoner i behandling av depresjon, særlig når selvhjelpsbehandlingen er veiledet av en terapeut. Forskning antyder også at behandlingseffektene kan være positive ved bruk i primærhelsetjenesten.

En randomisert kontrollert studie ble gjennomført ved UiT Norges Arktiske Universitet for å sammenligne veiledet selvhjelp bestående av MoodGYM og korte samtaler med psykolog, med en kontrollgruppe som sto på venteliste til å motta samme behandling. Deltakerne (n = 106) var pasienter med milde til moderate depresjonssymptomer rekruttert fra allmennpraksis. Resultatene viste at sammenlignet med kontrollgruppen reduserte behandlingen symptomer på depresjon, engstelse og bekymring, samt økte deltakernes livskvalitet. Oppfølging 6 måneder etter endt behandling tydet på at de positive effektene i stor grad hadde vedvart. Det var ingen forskjeller i behandlingseffekt mellom kvinner og menn eller for pasienter i ulike aldersgrupper. Behandlingseffekten var heller ikke påvirket av depresjonssymptomenes alvorlighetsgrad ved behandlingens oppstart, eller av hvorvidt deltakerne hadde komorbid angst. Frafallet fra intervensjonen var moderat og deltakernes vurdering av behandlingen var overveiende positiv.

Behandlingsmodellen ble introdusert til en gruppe allmennleger gjennom et 3-dagers kurs. Etter å ha gjennomført kurset anbefalte de fleste legene MoodGYM til pasientene sine. Legene opplevde programmet som et nyttig verktøy for å gi pasienter tilgang til evidensbasert

psykoedukasjon og selvhjelpsstrategier, samt for å aktivere dem i behandlingsprosessen. Oppfølgingssamtaler ble imidlertid lite brukt på grunn av tidspress, konkurrerende oppgaver og for liten kunnskap om programmet, samt manglende praktisk trening i gjennomføringen av slike samtaler.

Samlet indikerer disse funnene at intervensjonen kan være en effektiv behandling for depresjon og at mange pasienter kan være positive til en slik behandlingsmodell. Kursing av leger i bruk av intervensjonen kan fremme endring av praksis i form av å anbefale MoodGYM til pasienter, men andre tilnærminger er nødvendig for å fremme bruk av oppfølgingssamtaler. Dette kan trolig oppnås gjennom mer omfattende opplæringsprogrammer for leger med særlig interesse for feltet. Mer vidtrekkende implementering av behandlingsmodellen vil imidlertid kreve en mer sammensatt innsats med fokus på opplæring av både leger og pasienter, samt strukturelle endringer slik som endringer i finansieringsstrukturer. Andre lands erfaringer tyder på at opplæring av andre yrkesgrupper i primærhelsetjenesten til å gjennomføre veiledet internettbasert selvhjelp og lignende behandlingsmetoder også kan fremme effektiv implementering av slike helsetjenester.

Summary

The overall aim of this thesis was to explore the effectiveness and acceptability of a Web-based self-help program (MoodGYM) combined with brief face-to-face therapist support for adult primary care patients with mild to moderate depression.

Depression is a highly prevalent disorder causing substantial suffering and impairment of daily life. Many patients with mild to moderate depression will receive most or all of their mental health care from primary health care. Structured psychological interventions are infrequently delivered in general practice, despite the development of several effective psychological therapies for depression, patients' preferences for such treatments, and last but not least, guideline recommendations. During the last decade several internet-based interventions based on cognitive behavioural therapy (CBT) have been developed. Studies indicate that guided internet-based treatments yield moderate to large treatment effects for depression and outperform unguided interventions concerning effect and adherence. In addition, previous research supports the effectiveness of internet-based CBT when delivered in primary health care.

A randomised controlled trial was conducted at UiT The Arctic University of Norway to compare the guided internet-based intervention comprising MoodGYM and face-to-face therapist support with a waitlist control group. Participants (n = 106) were primary care patients with mild to moderate depressive symptoms. Results indicated that the intervention was effective in reducing symptoms of depression and anxious worry and in increasing life satisfaction. Treatment gains were largely maintained at 6-month follow-up. Treatment effects appeared to be comparable for men and women, for patients of various ages, and for patients with varying levels of pre-treatment depressive severity. In addition, comparable effects were found for patients with and without comorbid anxiety. Moderate levels of non-adherence and predominately positive ratings of treatment satisfaction indicated that the intervention was acceptable to patients.

The intervention was introduced to general practitioners (GPs) through a 3-day educational course focusing on CBT and MoodGYM in general practice. Following the course most GPs recommended MoodGYM to their patients. They valued that the program provided patients with evidence-based psychoeducation and self-help strategies and empowered them to take active part in their recovery process. However, follow-ups were not successfully implemented due to limiting factors such as time constraints, competing tasks and inadequate module knowledge and practical training.

Taken together these results indicate that the intervention may be effective and acceptable to primary care patients with mild to moderate depressive symptoms. A short educational course for GPs may promote recommendation of the program, but other approaches are needed to implement the full intervention including follow-ups. More comprehensive educational approaches may reach a selected group of GPs. However, multifaceted interventions including patient education, clinician education and organisational changes such as changing reimbursement structures are necessary to implement such interventions more widely. Experiences from other countries indicate that training other professional groups to deliver interventions such as guided internet-based CBT in primary care or in collaboration with specialised services may be one way to achieve successful implementation.

Abbreviations

ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
ANU	Australian National University
AUDIT	Alcohol Use Disorders Identification Test
BAI	Beck Anxiety Inventory
BDI	Beck Depression Inventory
BDI-II	Beck Depression Inventory-II
CBT	Cognitive Behavioural Therapy
DUDIT	Drug Use Disorders Identification Test
EQ-5D	EuroQol 5-Dimension Self-Report Questionnaire
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
IAPT	Improving Access to Psychological Therapy
IPT	Interpersonal Therapy
ITT	Intention-to-treat
LOCF	Last Observation Carried Forward
MAR	Missing at Random
MCAR	Missing Completely at Random
MNAR	Missing Not at Random
NPT	Normalization Process Theory
RCT	Randomised Controlled Trial
REML	Restricted Maximum Likelihood Estimation
SWLS	Satisfaction With Life Scale
WHO	World Health Organization

Introduction

Overview

Depression is one of the most prevalent mental disorders. European epidemiological studies show a 12-month prevalence for depression of up to 7 % for men and 11 % for women (Ayuso-Mateos et al., 2001; Kringlen, Torgersen, & Cramer, 2001; Wittchen & Jacobi, 2005; Wittchen et al., 2011). The projected lifetime risk is between 20 % and 30 % for any mood disorder as estimated by the World Health Organization's (WHO) World Mental Health Survey (Kessler et al., 2007). Depression causes substantial impairment in multiple areas of functioning, reduction in quality of life, and increases in medical service utilisation (Beesdo & Wittchen, 2008; Greenberg et al., 1999; Kilbourne, Daugherty, & Pincus, 2007; Mendlowicz & Stein, 2000; Wittchen & Jacobi, 2005; Wittchen et al., 2011). The disorder produces the greatest decrement in health compared to other chronic conditions, such as diabetes, angina, asthma and arthritis (Moussavi et al., 2007), and is also associated with increased mortality (R. Schulz, Drayer, & Rollman, 2002; Wulsin, Vaillant, & Wells, 1999). Depressive symptoms alone and in combination with anxiety symptoms are associated with a higher risk of sick leave (Brage, Nossen, Kann, & Thune, 2012; Knudsen, Harvey, Mykletun, & Øverland, 2013; Lexis, Jansen, van Amelsvoort, van den Brandt, & Kant, 2009; Stansfeld, Fuhrer, & Head, 2011). In fact, unipolar depression has been characterised by the WHO as a leading cause of disability, social and economic burden, affecting about 121 million people worldwide (2009). In addition, studies suggest that subthreshold depression is highly prevalent and associated with significant impairment in physical and emotional well-being, and everyday functioning, as well as increased use of health services (Backenstrass et al., 2006; J. Johnson, Weissman, & Klerman, 1992; Lecrubier, 2007; Rapaport & Judd, 1998).

Despite the development of several effective psychological and pharmacological treatments for depression (Cuijpers, van Straten, Andersson, & van Oppen, 2008; Cuijpers, van Straten, van Oppen, & Andersson, 2008), many of those suffering from the disorder receive inadequate or no treatment at all (Bebbington, Brugha, et al., 2003; Kessler et al., 2001). This situation led a work group commissioned by the US National Institute of Mental Health to recommend that future research and innovation give priority to the use of non-traditional delivery methods as a means to increase accessibility of treatment (Hollon et al., 2002). This thesis investigates if a novel approach to treatment using a Web-based self-help program can represent an effective treatment for mild to moderate depression.

Depressive Disorders

Major depressive disorder is characterised by emotional, cognitive, somatic and motivational symptoms, and the core symptoms are depressed mood and loss of interest or pleasure in all, or almost all, activities (American Psychiatric Association, 2013; World Health Organization, 2000). Other symptoms include loss of energy, low self-esteem, feelings of worthlessness or guilt, diminished ability to concentrate, sleep disturbances, changes in appetite or weight, and recurrent thoughts of death or suicide. In addition, social withdrawal and neglect of activities previously considered to be pleasurable is common (American Psychiatric Association, 2013). When several of these symptoms co-occur, are persistent for two weeks or more, and cause significant distress or interfere with the activities of daily life, the condition can be considered a major depressive episode and may require treatment. Current guidelines diagnose depressive disorders within a categorical framework where individuals are categorised as depressed or not depressed (American Psychiatric Association, 2013; World Health Organization, 2000). This implies that the disorder is qualitatively distinct from normal affective states, such as sadness and transient dysphoria; feelings all people experience to some degree from time to time. However, research indicates that the construct of depression is better understood as dimensional, with symptoms varying along a continuum of severity, and major depression being only quantitatively distinguishable from normal mood states (A. M. Ruscio & Ruscio, 2002; J. Ruscio & Ruscio, 2000).

The prevalence of depression is low in childhood, with point prevalence generally falling below 3 % (P. Cohen et al., 1993; Costello, Mustillo, Erkanli, Keeler, & Angold, 2003; Fleming & Offord, 1990; Hankin et al., 1998; Zalsman, Brent, & Weersing, 2006). During puberty there is a marked increase in incidence, and many experience their first depressive episode during the adolescent years (P. Cohen et al., 1993; Costello et al., 2003; Hankin et al., 1998; Kim-Cohen et al., 2003). Studies show a peak in risk for onset during the adolescent and early adult years (Burke, Burke, Regier, & Rae, 1990; Kim-Cohen et al., 2003). However, the onset of the disorder may occur at any age, and even though the new case incidence declines during the adult years, a first onset in late life does occur (Blazer, 2003; Burke et al., 1990).

There is a well-documented female preponderance in depression starting in adolescence, with a mean gender ratio of 2:1 (Bebbington, 1996; P. Cohen et al., 1993; Hankin et al., 1998; Kuehner, 2003). The course of depression varies, with some experiencing only a single episode, whereas others have a more chronic course with persistent symptoms or several recurring episodes. Unfortunately, recurrence is often the rule with studies showing

that about 50 % of patients relapse within 2 years of recovery, and 50 % to 85 % experience recurrence within longer periods of follow-up (Belsher & Costello, 1988; Kocsis, 2006; Maj, Veltro, Pirozzi, Lobrace, & Magliano, 1992; Mueller et al., 1999; Solomon et al., 2000). In addition, the number of prior episodes appears to progressively increase the risk of further recurrences, whereas with longer durations of recovery the risk of recurrence is reduced (Belsher & Costello, 1988; Maj et al., 1992; Mueller et al., 1999; Solomon et al., 2000). This point to the importance of prevention of recurrence and provision of highly accessible treatments that may prevent that recurring symptoms evolve into more severe forms of clinical depression.

Depression often co-occurs with other mental disorders. There is a high rate of comorbidity between depression and anxiety disorders (Kessler, Chiu, Demler, & Walters, 2005). Some argue that due to the substantial comorbidity and the similarities in defining features and risk factors, these disorders should form a common cluster of emotional disorders (Goldberg, Krueger, Andrews, & Hobbs, 2009). There is also strong associations between depression and alcohol and other substance use disorders (Swendsen & Merikangas, 2000), borderline personality disorder (Corruble, Ginestet, & Guelfi, 1996), and eating disorders (Hudson, Hiripi, Pope Jr, & Kessler, 2007).

A comprehensive account of risk factors for depression is outside the scope of this thesis, but some may be mentioned. Depression is a complex multifactorial disorder. This means that several risk factors, genetic and non-genetic, contribute to its development (Levinson, 2006). Stressful life events predict the onset of major depression (e.g., Kendler, Kuhn, & Prescott, 2004; Tennant, 2002). Findings indicate that among acute stressors the most recent events have the highest impact. However, adverse childhood experiences such as maladaptive family functioning and sexual abuse may render individuals vulnerable to depression, partly due to increased stress sensitivity (e.g., Green et al., 2010; Kendler et al., 2004; Maniglio, 2010). In addition, studies support the notion that dysfunctional cognitive schemas may increase the vulnerability for developing depression when faced with negative life events (Scher, Ingram, & Segal, 2005). Another factor increasing the risk for depression is the personality trait neuroticism (Hettema, Neale , Myers , Prescott , & Kendler 2006; Kendler, Gatz, Gardner, & Pedersen, 2006). This may partly be related to common genetic factors. Within the population, genetic factors account for about 30 % to 50 % of the variation in susceptibility to depression (Levinson, 2006; Sullivan, Neale, & Kendler, 2000). Several genes have been investigated, and some studies support a gene-environment interaction where

a variation in the serotonin transporter gene (5-HTT) moderates the impact of stressful life events on depression (Caspi et al., 2003; Kendler, Kuhn, Vittum, Prescott, & Riley, 2005).

Treatments for Depression

There exist several effective pharmacological and psychological therapies for depression (Cuijpers, van Straten, van Oppen, et al., 2008). Apparently, there are no large differences in treatment effects between psychological and pharmacological therapies for patients with major depression. Furthermore, there is no compelling evidence to suggest that psychological therapies are insufficient for patients with more severe depression compared to pharmacotherapy. However, combining psychological and pharmacological therapy may result in a small benefit in the short term (Cuijpers, van Straten, Warmerdam, & Andersson, 2009). Some meta-analyses point to a limited effect of antidepressants for milder depressive states (Fournier, DeRubeis, Hollon, & et al., 2010; Kirsch et al., 2008). The difference between antidepressants and placebo is very small for mild to moderate depression, and larger effects are only found for severely depressed patients.

Studies generally suggest that a range of psychological therapies can be effective in treating depression (Churchill et al., 2001). This includes therapies originating from different theoretical traditions, including cognitive behavioural therapy (CBT), behavioural activation, interpersonal therapy (IPT) and psychodynamic therapy. Comparative studies of different psychotherapies have yielded limited evidence for any therapy being superior (Cuijpers, van Straten, Andersson, et al., 2008; Dimidjian et al., 2006; Jakobsen, Hansen, Simonsen, Simonsen, & Gluud, 2012; Power & Freeman, 2012; Wampold, Minami, Baskin, & Callen Tierney, 2002; Wampold et al., 1997). Some findings suggest that IPT may be somewhat more effective than other therapies, and that non-directive supportive therapy may be somewhat less effective (Cuijpers et al., 2012; Cuijpers, van Straten, Andersson, et al., 2008). However, differences are small and probably of limited significance from a clinical point of view. The claim that all psychological therapies are equally effective has been referred to as the "Dodo Bird Verdict" which states that "everybody has won and all must have prices" (Wampold et al., 1997). This diversity of effective treatments is also reflected in clinical guidelines recommending both CBT, IPT, behavioural activation and short-term psychodynamic psychotherapy (Helsedirektoratet, 2009; National Institute for Health and Clinical Excellence, 2009). However, there may still be small differences in effect between therapies which meta-analyses to date have been unable to detect (Cuijpers, van Straten,

Andersson, et al., 2008). In addition, despite comparable effects different approaches may promote change through different mechanisms.

Cognitive Theory of and Therapy for Depression

Beck's cognitive theory emphasises the role of information processing in shaping our emotions (D. A. Clark, Beck, & Alford, 1999). Cognitive theory assumes two-way interactions between cognition, emotion and behaviour (A. T. Beck, 1963, 1964; D. A. Clark et al., 1999). People make meaning of situations and form cognitive representations that are influenced by the relevant context, but also by our cognitive structures (schemas) and previous experiences that have influenced the content of these structures. Thus, our affective and behavioural responses to the circumstances of everyday life are mainly dependent upon our cognitive representations of the situation rather than the situation itself. Accordingly, all human information processing represents to some degree a biased representation of reality. However, what distinguishes healthy information processing from that of psychopathological states is the presence of systematic processing errors, and whether the processing of information is influenced by dysfunctional schemas to a degree that hampers mastery and coping (A. T. Beck, Rush, Shaw, & Emery, 1979).

Schemas

Schemas play an important role in organising new information in a meaningful way and result in a unique and relatively enduring inclination of the individual to interpret experiences in certain ways (A. T. Beck, 1964; A. T. Beck et al., 1979). Their development is contingent on the external environment in such a way that schemas that are frequently activated due to life experiences become more elaborate and dominant. Schema development is also influenced by genetic or biological predispositions. Dysfunctional schemas may constitute a predisposition to depression (A. T. Beck et al., 1979).

The content of schemas differs in terms of level of abstraction (D. A. Clark et al., 1999). Simple schemas represent single objects or specific ideas. At the intermediate level schemas may take the form of conditional rules for how to evaluate oneself and others (e.g., "If I am criticised, then it means I have failed"), or imperative beliefs involving statements about "should" and "must" related to personal goals and values (e.g., "I must be liked by everyone I meet"; A. T. Beck, 1991; A. T. Beck, 1996; A. T. Beck et al., 1979). The most general schemas are the "core beliefs" which are usually expressed as absolute statements describing the self. In individuals predisposed to depression core beliefs involving

helplessness and unlovability, such as “I am worthless”, “I am inadequate” and “I am a failure”, may dominate the self-concept (D. A. Clark et al., 1999). These schemas tend to be rigid, absolute and not easily modified.

In depression, dysfunctional schemas are activated by negative life stressors (A. T. Beck, 1996; D. A. Clark et al., 1999). When activated they dominate the information processing at the expense of more constructive modes of thinking (A. T. Beck, 1964). The result is a negative view of the self, a tendency to interpret experiences in a negative way (negative view of the world) and pessimistic expectations about the future (A. T. Beck et al., 1979). These three cognitive patterns are referred to as the negative cognitive triad. Depression is maintained through a vicious cycle where the depressive mind-state becomes self-perpetuate due to the tendency of depressed individuals to selectively attend to information congruent with the depressive schemas (A. T. Beck, 1963, 1964; D. A. Clark et al., 1999). In addition, dysfunctional schemas become increasingly likely to be activated in a variety of situations by input from the external environment and by internal stimuli such as recall of past experiences or focus on one’s own thoughts, feelings or aspects of the self.

Negative automatic thoughts and cognitive distortions

The phenomena of negative automatic thinking and cognitive errors are highly characteristic of the depressed thinking style (A. T. Beck, 1963, 1991). Negative automatic thinking is brief, involuntary and spontaneous and runs in parallel to more deliberate and conscious thinking (A. T. Beck, 1991). These thoughts are biased interpretations of events, predictions, self-monitoring or self-instructions that are consistent with the individual’s mood state (A. T. Beck, 1991; J. S. Beck, 1995). In the case of depression these thoughts typically revolves around themes of personal defeat or failure. People are often scarcely aware of these thoughts and accept their content as true. The unpleasurable emotions that follow are, however, often readily experienced.

Cognitive errors refer to the systematic misrepresentation of reality, which is a result of the activation of dysfunctional schemas (A. T. Beck, 1963, 1964, 1991; A. T. Beck et al., 1979). Several typical errors have been identified, for example the tendency to selectively focus on a negative detail, such as personal failures and defects, and to ignore other relevant context information (mental filter/selective abstraction), the tendency to minimise or exaggerate the significance of an event (magnification/minimisation), or making generalisations based on a single incident (overgeneralisation). Another common error is the inclination to engage in dichotomous black-and-white thinking where a situation is construed

as categorical instead of as a continuum. This may lead to exaggerated conclusions such as: "If I am not a total success, I am a failure".

Cognitive therapy for depression

Cognitive therapy assumes that changes in dysfunctional cognitions and underlying cognitive structures are central to the improvement of depressive symptoms (A. T. Beck, 1964; A. T. Beck et al., 1979). A key goal in the treatment is to help the depressed individual to attend to and process schema-incongruent information and in this way deactivate the depressive mode of thinking (A. T. Beck, 1996; D. A. Clark et al., 1999). This may be achieved by identifying dysfunctional thoughts, patterns of cognitive distortions, and underlying assumptions and beliefs, and putting these thoughts under scrutiny to evaluate and challenge their validity and utility (J. S. Beck, 1995). Finally, alternative and more adaptive responses are developed. An important principle is collaborative empiricism which means that the therapist and patient work together through this process of cognitive restructuring (A. T. Beck et al., 1979; J. S. Beck, 1995). The therapist does not directly challenge the thoughts, but rather uses gentle questioning techniques to facilitate the patient's process. Therapy can, thus, be considered a learning process in which the patient learns to solve problems and view experiences in new ways in order to modify the predisposition to depression (A. T. Beck, 1991, 1996).

The therapy generally focuses on problems of the here-and-now, and the patient is encouraged to take actively part during therapy sessions and is expected to engage in homework exercises (A. T. Beck et al., 1979; J. S. Beck, 1995). Studies show that patients who adhere to homework assignments show better progress than those who do not (Detweiler & Whisman, 1999; Feng et al., 2012). Behavioural techniques are also often included, thereof the term cognitive behavioural therapy (A. T. Beck et al., 1979; J. S. Beck, 1995). In depression the non-adaptive behaviours of inactivity and rumination is targeted through activity monitoring and scheduling, and behavioural experiments may be used to directly test the accuracy of a thought or assumption.

The empirical status of cognitive theory and therapy

The effect of CBT is well documented. Several studies indicate that the effect of CBT is large in adult samples and comparable to the effects of pharmacotherapy and other effective psychological therapies, such as behaviour therapy and IPT (Butler, Chapman, Forman, & Beck, 2006; Churchill et al., 2001; Cuijpers, van Straten, Andersson, et al., 2008; Gloaguen, Cottraux, Cucherat, & Blackburn, 1998; Jakobsen et al., 2012). The therapy can also be

delivered effectively in a group format (Feng et al., 2012; Hans & Hiller, 2013), and positive, albeit more moderate effects have been found for adolescent depression (J. B. Klein, Jacobs, & Reinecke, 2007). Cognitive therapy is highly effective also when delivered in routine practice settings, although, effect sizes appear somewhat lower than in randomised trials (Forand, Evans, Haglin, & Fishman, 2011; Gibbons et al., 2010; Hans & Hiller, 2013). However, the positive effects of CBT are not indisputable, and two recent meta-analyses suggest that even though CBT may be an effective treatment compared to no intervention or usual care, effect sizes of previous reports may be overestimated due to a high risk of bias in most trials (Jakobsen, Hansen, Storebo, Simonsen, & Gluud, 2011a, 2011b).

There seems to be a preventive effect of CBT on relapse and recurrence, especially when continuation phase treatment is provided, and this effect extends beyond discontinuation of treatment and may be comparable to the effect of keeping patients on medications (Bockting et al., 2009; Gloaguen et al., 1998; Hollon et al., 2005; Hollon, Stewart, & Strunk, 2006; Vittengl, Clark, Dunn, & Jarrett, 2007). This is important as depression is often a recurrent disorder, and it suggests that CBT may teach patients compensatory skills that can be used effectively to reduce relapse and recurrence of the disorder (Hollon et al., 2006; Vittengl et al., 2007).

Research on the empirical status of the cognitive model is inconclusive, but generally supports an increase of negative thinking, preoccupation with loss and failures, as well as cognitive distortions in depression, although this does not seem to characterise all depressed individuals (D. A. Clark & Steer, 1996). Studies also support the notion of cognitive mediation in cognitive therapy, but results are not conclusive regarding the specificity of this mechanism, as cognitive changes seem to occur also in non-cognitive treatments (Driessen & Hollon, 2010; G. Garratt, Ingram, Rand, & Sawalani, 2007; Hollon & DeRubeis, 2009; Jacobson et al., 1996). In addition, research suggests that changes in underlying cognitive predispositions may play a role in preventing relapse (Driessen & Hollon, 2010; Hollon et al., 2006). Despite the extensive support for CBT, this treatment remains difficult to access, due to a limited number of trained therapists (Lovell & Richards, 2000).

Treatment of Depression in Primary Health Care

A large proportion of consultations in primary care are due to psychological problems, and many patients will receive most or all of their mental health care in primary care (Kovess-Masfety et al., 2007; Wang et al., 2007; Wittchen et al., 2011; Wittchen & Pittrow, 2002; Young, Klap, Sherbourne, & Wells, 2001). In Norway the general practitioner (GP) is a

central provider of primary care services, and general practice is organised as a listed patient system where each GP has a list of patients to whom he/she provides health care (Helse- og Omsorgsdepartementet, 2014). On average Norwegian GPs have a list of approximately 1300 patients (Grytten, Skau, Sørensen, & Aasland, 1999). This system has the advantage that patients and even families can consult the same GP for a range of problems over several years. This may result in more efficient health care delivery and better continuity of care, especially for chronically ill patients. It also allows for the establishment of a trusting and therapeutic doctor-patient relationship (Davidsen & Reventlow, 2010). Getting to know the patient's story over time can also enable the GP to see the patient's symptoms in relation to their whole life situation of current and past experiences (Davidsen, 2009)

General practice is characterised by time pressure and complex consultations (Murray et al., 2010). Consultations generally last from 15 to 20 minutes, and within this time patients may present several problems, including both somatic and mental issues. The majority of Norwegian GPs are self-employed physicians who work on a fee-for-service contract with the municipality, and their income is mainly based on National Insurance reimbursements and patient co-payments (Statistics Norway, 2014). Reimbursement schemes support the use of various diagnostic and treatment procedures, but generally encourage short consultations and treating many patients (Aschim, Lundevall, Martinsen, & Frich, 2011; Grytten et al., 1999; Mykletun, Knudsen, Tangen, & Øverland, 2010). This is a barrier for investing time to treat mentally ill patients or learning new methods. Recently, prolonging consultations to 25 minutes when using structured therapy has become supported, but longer time per patient may mean longer waitlists for other patients, and this may be a limiting factor. However, the possibility of seeing patients again and again over long periods can to some extent compensate for the lack of time during consultations (Davidsen & Reventlow, 2010).

The GP serves as a gatekeeper to all specialised services, including specialised mental health care. However, for many patients access to specialised treatment for depression is limited due to long waitlists (Helsedirektoratet, 2014). In studies both in Norway and other Western societies GPs report that long waitlists and a lack of collaboration with specialised mental health care are important factors hindering optimal treatment of mental disorders (Fleury, Imboua, Aube, Farand, & Lambert, 2012; Mykletun et al., 2010; Sinnema et al., 2013).

Recognition and diagnosis

In order to avert the development of more serious psychological and social problems while waiting for treatment, patients should receive quality services in primary care at an early stage (Moore, 1997). However, several studies suggest that the recognition and treatment of depression in primary care is less than optimal (González et al., 2010; Simon, Fleck, Lucas, Bushnell, & Lido Group, 2004; Wittchen et al., 2002; Young et al., 2001). Two meta-analyses conclude that GPs' sensitivity to detect depression is rather low, between 36 % and 50 %, suggesting that GPs generally can identify depression in half or less of true cases (Cepoiu et al., 2008; Mitchell, Vaze, & Rao, 2009). The specificity is higher, and GPs can accurately exclude approximately 80 % of non-depressed individuals. These findings are generally supported by results from three large scale European studies (Lecrubier, 2007).

Some studies suggest that more severe cases of depression with more extensive disability and comorbidity seem to be more reliably detected, diagnosed and adequately treated than less severe forms (Hyde et al., 2005; Lecrubier, 2007; Simon & Von Korff, 1995; Wang, Berglund, & Kessler, 2000; Wittchen & Pittrow, 2002). This may reflect treatment matching by primary care physicians with a reasonable accuracy in identifying patients who have a high likelihood of spontaneous recovery. This is supported by research showing similar outcomes for unrecognised and untreated compared to recognised and treated patients (Simon & Von Korff, 1995; Tiemens, Ormel, & Simon, 1996). However, others have found that appropriate treatment is more often delivered when the condition is recognised as depression (Lecrubier, 2007; Wittchen & Pittrow, 2002), and that patients who are given an appropriate diagnosis experience better outcomes (Simon, Goldberg, Tiemens, & Ustun, 1999; J. W. Williams et al., 1999).

Treatment

Clinical practice guidelines primarily recommend psychosocial interventions as the first line of treatment for subthreshold, mild and moderate depression (Helsedirektoratet, 2009; National Institute for Health and Clinical Excellence, 2009). Consistent with evidence showing that antidepressant medications do not outperform placebo for mild states of depression (Fournier et al., 2010; Kirsch et al., 2008), antidepressants are not recommended as routine treatment for these conditions (Helsedirektoratet, 2009; National Institute for Health and Clinical Excellence, 2009). The guidelines are also in accordance with studies showing that patients generally prefer psychological therapy, counselling or psychoeducation to medication (Angermeyer & Matschinger, 1996; Priest, Vize, Roberts, Roberts, & Tylee,

1996; Prins, Verhaak, van der Meer, Penninx, & M, 2009; van Schaik et al., 2004). Findings also suggest that many patients prefer to consult their GP for treatment (Bebbington, Meltzer, et al., 2003; Jorm, 2000). Seeking help from a GP has the advantages of being more accessible, affordable, and less stigmatising than specialised mental health services (Keks, Altson, Sacks, Hustig, & Tanaghow, 1997).

Unfortunately, several investigations confirm that the proportion of patients with depression receiving active or guideline-concordant treatment in primary care is low to moderate, ranging from 15 % to 65 % (González et al., 2010; Hyde et al., 2005; Kendrick, King, Albertella, & Smith, 2005; Wang et al., 2007; Wittchen & Pittrow, 2002). Even when primary care physicians are notified of the patient's diagnosis, this does not seem to be sufficient to ensure adequate treatment (Simon et al., 2004; Whooley, Stone, & Soghikian, 2000; J. W. Williams et al., 1999).

Despite recommendations, structured psychological interventions are rarely delivered in general practice (Davidsen, 2008; King et al., 2002). This is due to time constraints (Aschim et al., 2011; Backenstrass, Joest, Rosemann, & Szecsenyi, 2007; Fleury et al., 2012; Mykletun et al., 2010; Telford, Hutchinson, Jones, Rix, & Howe, 2002; Wiebe & Greiver, 2005), and a lack of knowledge and competence among GPs in the delivery of evidence-based psychological interventions (Davenport, Morgan, Parsons, Hickie, & Blashki, 2003; Mykletun et al., 2010). Treatment of depression in general practice is, therefore, often limited to open listening, informal supportive therapy, prescription of medication, brief psychoeducation and provision of medical certificates or referrals (Backenstrass et al., 2007; Davidsen, 2008; Fleury et al., 2012). Throughout the last decades there has been a huge increase in the use of antidepressant medications (Rønning et al., 2009), and despite their limited effect for milder depressive states, antidepressants are widely prescribed for mood disorders in primary health care (Alonso et al., 2004; W. D. Robinson, Geske, Prest, & Barnacle, 2005; Sinnema et al., 2013).

Stepped Care Models

The treatment gap and the lack of implementation of treatment guidelines for mental health care have become increasingly acknowledged internationally (Layard et al., 2006; World Health Organization & World Organization of Family Doctors, 2008). The WHO has suggested that integration of mental health in primary care is the most viable solution to ensure access at an affordable cost (World Health Organization & World Organization of

Family Doctors, 2008). Others call for novel ways of delivering psychological services in order to improve access (Layard et al., 2006; Lovell & Richards, 2000).

Stepped care models of health care delivery have been proposed to amend the problem of poor access to adequate services (Haaga, 2000). These models take into account that not all patients will need the same intensity of treatment and attempt to allocate resources in a way that ensures both cost-efficiency and delivery of evidence-based treatment to a maximum number of patients. Patients will first be offered the least intensive of effective treatment options and will only be presented with more intense treatments if the first intervention yields insufficient treatment gains (Davison, 2000). The lower steps are typically least expensive in terms of cost for the individual and society, least intrusive in terms of inconvenience for the patient, and have the lowest intensity with regard to the amount of specialist therapist time required to deliver the intervention (Bower & Gilbody, 2005). Another key-feature of stepped-care is that the model is self-correcting (Bower & Gilbody, 2005). Because treatment strategies are systematically evaluated through close monitoring of progress, decisions to make treatment changes ("stepping-up") can be made readily if one step does not produce the desired effect.

There is no clear consensus on the number of steps, and the content may include a variety of treatments of differing intensity, based on various theoretical models and delivered by practitioners of different levels of expertise (Bower & Gilbody, 2005). Since as many as 50 % of individuals experiencing a depressive episode may spontaneously recover within 3 months (Spijker et al., 2002), watchful waiting or active monitoring may be included as a first step for patients with mild to moderate depressive symptoms before introducing formal interventions (National Institute for Health and Clinical Excellence, 2009; D. A. Richards et al., 2012; van Straten, Seekles, van't Veer-Tazelaar, Beekman, & Cuijpers, 2010). This may include symptom and risk assessments, psychoeducation, provision of support and a plan for further appointments. If symptoms persist, the patient may be offered a range of low-intensity treatments, including (internet-based) self-help interventions with or without guidance from a therapist (D. M. Clark, 2011; Gidding, Spigt, & Dinant, 2014; D. A. Richards et al., 2012; Scogin, Hanson, & Welsh, 2003; van Straten et al., 2010). Brief evidence-based psychological therapy or group-based CBT delivered by a primary care therapist can also be considered low-intensity treatments (Gidding et al., 2014; D. A. Richards et al., 2012; van Straten et al., 2010). In general, high-intensity interventions include more prolonged psychological therapy delivered in specialist mental health care, antidepressant medication, combination treatments, and hospitalisation (Bower & Gilbody, 2005; National Institute for Health and Clinical

Excellence, 2009; D. A. Richards et al., 2012). Ideally, patients should be assigned to specific steps on the basis of knowledge about which patients who are more likely to benefit from which treatments (Haaga, 2000). There is to date little evidence to guide such decisions, nevertheless it is generally recommended to assign patients with more severe or complex depression directly to high-intensity services (Haaga, 2000; National Institute for Health and Clinical Excellence, 2009; Scogin et al., 2003). Patient preference must of course also be taken into account (van Straten et al., 2010).

The stepped-care approach is becoming implemented in guidelines for depression care (National Institute for Health and Clinical Excellence, 2009; New Zealand Guidelines Group, 2008; Sinnema et al., 2013; The National Board of Health and Welfare (Socialstyrelsen), 2004). In the UK the Improving Access to Psychological Therapy (IAPT) program is a large-scale initiative to train new therapists and establish new clinical services delivering evidence-based psychological therapy in accordance with the principles of stepped-care (D. M. Clark, 2011; D. A. Richards et al., 2012). Studies from the rollout of the program show that even though guidelines are implemented in very different ways between sites, outcomes are positive with regard to recovery, patient throughput and number of individuals moved off sick pay/ state benefits (D. M. Clark, 2011; D. M. Clark et al., 2009). Also in the Netherlands there has been extensive focus on the implementation of stepped-care for depression in primary care (Franx et al., 2009; Gidding et al., 2014; Seekles, van Straten, Beekman, van Marwijk, & Cuijpers, 2011). The model appears to be acceptable and feasible for practitioners, and introducing guidelines and quality improvement programs seem to positively affect regular practice by increasing the delivery of low-intensity interventions for non-severe cases (Franx et al., 2009; Gidding et al., 2014; Hermens, Muntingh, Franx, van Splunteren, & Nuyen, 2014; Sinnema et al., 2013). There is, however still room for improvement, especially with regard to increasing the use of (online) self-help and decreasing the use of antidepressant medication as an initial intervention (Franx, Oud, de Lange, Wensing, & Grol, 2012; Gidding et al., 2014; Hermens et al., 2014; Sinnema et al., 2013).

Despite these strides taken towards embracing stepped-care in regular practice, results of studies comparing the effect of stepped-care to usual care in randomised trials have been mixed (Seekles et al., 2011; van't Veer-Tazelaar et al., 2009). Further research is necessary to establish an optimal model for treatment delivery encompassing the most effective and acceptable treatment steps.

Self-help Approaches in Treatment

Emphasise on low-intensity treatments in current guidelines actualise efforts to validate self-help treatments. Bibliotherapy was defined by Marrs (1995) as a treatment which relies on the use of written materials, computer/internet-based programs or audio/video-recorded materials with the aim of understanding or solving problems relevant to an individual's therapeutic needs. The following discussion will pertain to self-help as defined by Marrs (1995). Self-help groups, in which individuals sharing a common problem meet without involvement or guidance from professional therapists, are outside the scope of this thesis.

The focus on development of written self-help manuals started in the 1970s, and already in the late 1970s Glasgow and Rosen reviewed the literature on self-help manuals for a variety of problems (1978). Later, meta-analyses focusing specifically on depression reported that treatments using written or audio-recorded self-help material were effective (Cuijpers, 1997; Den Boer, Wiersnia, & Van den Bosch, 2004; Gellatly et al., 2007). During the 1990s and, especially, after the turn of the millennium research has increasingly focused on computerised or internet-based self-help programs. To date, treatments using computer- or internet-based programs have shown significant positive effects for a wide range of psychological disorders, including depression (e.g., Johansson, Ekbladh, et al., 2012; Ruwaard et al., 2009), relapse prevention for partially remitted depression (Holländare et al., 2011), social phobia (e.g., Furmark et al., 2009; Hedman et al., 2011; Marks, Kenwright, McDonough, Whittaker, & Mataix-Cols, 2004), panic disorder with or without agoraphobia (e.g., Kiropoulos et al., 2008; Nordgreen et al., 2010; Silfvernagel et al., 2012), generalised anxiety disorder (Mewton, Wong, & Andrews, 2012), obsessive-compulsive disorder (B. Klein, Meyer, Austin, & Kyrios, 2011), posttraumatic stress disorder (Lange et al., 2003; Spence et al., 2014), problematic alcohol or substance use (Campbell et al., 2014; Kay-Lambkin, Baker, Lewin, & Carr, 2009; Riper et al., 2008; Tait, Spijkerman, & Riper, 2013), eating disorders (Aardoom, Dingemans, Spinhoven, & Van Furth, 2013; Dölemeyer, Tietjen, Kersting, & Wagner, 2013), insomnia (Van Straten et al., 2014), chronic pain (Buhrman et al., 2013; Dear, Titov, et al., 2013), and chronic somatic conditions (Van Beugen et al., 2014). In addition to being used to treat disorders, internet-based programs have also been widely used for prevention purposes (e.g., Calear, Christensen, Mackinnon, Griffiths, & O'Kearney, 2009). However, as the main focus of this thesis is on treatment, I will limit my discussion to internet-based treatments.

Self-help therapies provide an alternative to regular specialised mental health care which typically have limited capacity, and can reach individuals who are resistant to seek help

through regular services (K. A. Collins, Westra, Dozois, & Burns, 2004; Mohr et al., 2010). A Norwegian population study found that only 13 % of those with depressive symptomatology had ever sought help for mental problems (Roness, Mykletun, & Dahl, 2005). Barriers to seeking treatment may be fear of stigma associated with mental health problems, lack of time, negative stereotypes of treatment, unwillingness to disclose problems and a desire to handle problems on one's own (K. A. Collins et al., 2004; Cuijpers, 1997; Roness et al., 2005). Self-help treatments have the advantages of being widely available as they can be accessed from anywhere at any time without the limitations of opening hours, geographic distance, mobility constraints or variations in the availability of specialised services in the local community. Self-help can allow for anonymity, which for some individuals may reduce barriers to help-seeking. Another advantage compared to face-to-face treatments is that patients have the opportunity to work through the material at their own pace and in the comfort of their own home (Andersson, Hesser, Veilord, et al., 2013; Beattie, Shaw, Kaur, & Kessler, 2009; MacGregor, Hayward, Peck, & Wilkes, 2009). In addition, it is possible to repeat and reflect on material both during and after the acute treatment-phase which may reinforce learning and facilitate maintenance of treatment gains (Andersson & Titov, 2014).

Internet-based Treatment for Depression

The majority of self-help programs for depression are based on the principles of CBT (D. Richards & Richardson, 2012). The structure, well-defined techniques and the focus on homework and patient engagement makes this treatment especially suitable for the self-help format (Proudfoot, 2004). However, recently there has been an increase in research on programs based on other treatment approaches such as psychodynamic therapy (Johansson, Ekbladh, et al., 2012), problem-solving therapy (van Straten, Cuijpers, & Smits, 2008; Warmerdam, van Straten, Twisk, Riper, & Cuijpers, 2008), interpersonal therapy (Donker, Bennett, et al., 2013), and acceptance and commitment therapy (Carlbring et al., 2013; Lappalainen et al., 2014). Online self-help usually comprises structured modules presenting similar content as covered in standardised face-to-face treatment: psychoeducation, treatment rationale and specific techniques, such as cognitive restructuring and behavioural activation, as well as exercises and homework tasks to facilitate understanding and promote change (Cowpertwait & Clarke, 2013; D. Richards & Richardson, 2012). Patients access this material by logging on to a secure website. A typical intervention has a duration of approximately 10 weeks, and patients are meant to use specific program content each week (Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012). However, other ways of delivering interventions are

emerging, such as the SilverCloud platform where patients can create their own personal home page from which they can access module content, interactive elements and applications in any order they wish, as well as receiving professional and peer support (Sharry, Davidson, McLoughlin, & Doherty, 2013).

The importance of guidance

Online self-help can be self-administered or guided by a therapist. In self-administered treatments the self-help program alone constitutes the treatment, and there is no involvement of a therapist, whereas guided self-help includes some therapist involvement, though to a lesser extent than in conventional psychological therapy (Cuijpers, Donker, van Straten, Li, & Andersson, 2010). The purpose of the guidance is primarily to support patients in working through the self-help program, but guidance may also include focus on process issues, such as setting goals and discussing treatment strategies. It may include real-time (synchronous) interaction, such as messenger services, phone-calls or brief meetings, or delayed (asynchronous) interaction, such as e-mail contact (Andersson & Titov, 2014).

There is substantial evidence indicating that interventions offering some degree of support during treatment generally show significantly larger treatment effects than interventions without support (Cowpertwait & Clarke, 2013; Johansson & Andersson, 2012; D. Richards & Richardson, 2012; Spek et al., 2007). Results from studies directly comparing guided and unguided interventions have found small differences (Berger, Hammerli, Gubser, Andersson, & Caspar, 2011; Farrer, Christensen, Griffiths, & Mackinnon, 2011), but a recent review of such comparative studies concluded that guided interventions were more effective (Baumeister, Reichler, Munzinger, & Lin, 2014). Some studies of unguided interventions have yielded large treatment effects (Farrer et al., 2011; Lintvedt, Griffiths, Sørensen, et al., 2013), but generally self-administered, unguided CBT produces small to moderate effects in the treatment of depression (Christensen, Griffiths, Korten, Brittliffe, & Groves, 2004; Clarke et al., 2009; Cuijpers et al., 2011; Meyer et al., 2009; D. Richards & Richardson, 2012; Titov, 2011). Unguided treatments may, nevertheless, be useful in a public health perspective as they are highly accessible at low-cost (Andersson, 2009; Lintvedt, Griffiths, Sørensen, et al., 2013).

Guided interventions overall show moderate to large treatment effects for depression, and the average effect sizes are comparable to the effects of time-limited individual or group face-to-face treatments (e.g., Andersson et al., 2005; Arnberg, Linton, Hultcrantz, Heintz, & Jonsson, 2014; Berger et al., 2011; Perini, Titov, & Andrews, 2009; D. Richards &

Richardson, 2012). This conclusion is supported both by trials comparing guided self-help and face-to-face treatments (Andersson, Hesser, Veilord, et al., 2013; Wagner, Horn, & Maercker, 2014; Wright et al., 2005) and by a meta-analysis (Cuijpers et al., 2010). There is, however, no clear consensus on what constitutes the optimal amount and content of support or what is the necessary level of qualifications for therapists. Studies suggest that for highly structured self-help programs, guidance provided by a professional clinician or by technicians or administrative staff receiving clinical supervision may result in similar outcomes (D. Richards & Richardson, 2012; Titov et al., 2010).

Studies supporting the long-term benefits of guided internet-based self-help are emerging (Andersson, Hesser, Hummerdal, Bergman-Nordgren, & Carlbring, 2013; Andersson, Hesser, Veilord, et al., 2013), as are studies showing that this mode of treatment may be successfully transferable to regular primary or secondary care settings (Cavanagh, Seccombe, & Lidbetter, 2011; Hedman et al., 2014; Newby, Mewton, Williams, & Andrews, 2014; Ruwaard, Lange, Schrieken, Dolan, & Emmelkamp, 2012). Research also suggests that internet-based interventions may be cost-effective compared to face-to-face treatments or usual care (Hollinghurst et al., 2010; Marks et al., 2003; McCrone et al., 2004; Warmerdam, Smit, van Straten, Riper, & Cuijpers, 2010), but a recent systematic review concluded that the quality of evidence is still too weak to draw firm conclusions on this point (Arnberg et al., 2014). Despite largely positive results, the last word has not been said about the effect of internet-based treatments. A meta-analytic re-evaluation pointed to high attrition rates, methodological problems, the likely presence of publication bias, and the lack of significant functional improvements which are critical for cost-utility (So et al., 2013). They concluded that previous effect estimates may be overestimated and that the true effect may be significant, but small. However, this study did not distinguish between studies with and without support, which may have affected the overall results.

Treatments for specific subgroups

Studies are starting to explore the utility of internet-based approaches for various subgroups of patients. Studies of internet-based interventions for children and youth are still scant, and a recent review concluded that there is to date no support for significant effects of such interventions targeting depression in this age group (Ye et al., 2014). Results from an open study of older adults, on the other hand, showed promising results both with regard to improvement, adherence and acceptability (Dear, Zou, et al., 2013).

The high rates of comorbidity between depression and especially anxiety disorders, have spurred efforts to develop effective approaches to address this issue (Andersson & Titov, 2014). Tailored programs individualise the treatment by presenting material tailored to the patient's symptom profile and capacity (Johansson, Sjöberg, et al., 2012). A second approach uses transdiagnostic programs which synthesise the common elements of CBT for depression and anxiety disorders in a single program (Titov et al., 2011). Both approaches have proved effective in controlled studies (Johansson, Sjöberg, et al., 2012; Newby et al., 2013; Titov et al., 2011). However, less is known about the relative effect compared to standardised diagnosis-specific treatment (Craske et al., 2007; Johansson, Sjöberg, et al., 2012).

The role of the therapeutic alliance

The therapeutic alliance is seen as an essential common factor contributing to a positive outcome in face-to-face therapy (Horvath & Symonds, 1991; Martin, Garske, & Davis, 2000). Since the beginning, a common question in research on internet-based interventions has been if a therapeutic alliance can be facilitated when no or limited therapist input is provided and in the absence of social cues (Cook & Doyle, 2002). In the meantime, studies have shown that a strong working alliance may develop even in treatments including only text-based communication, and the strength of the alliance may be comparable to face-to-face treatment (Knaevelsrud & Maercker, 2007; Preschl, Maercker, & Wagner, 2011). It is indeed, argued that even standardised text-based material may incorporate therapeutic factors through the use of comments conveying belief in recovery and treatment credibility and by using case stories to display empathy, warmth and genuineness (Richardson, Richards, & Barkham, 2010). Compared to results from face-to-face treatments, therapist factors and working alliance in online therapy seem to be less predictive of outcome (Almlöv, Carlbring, Berger, Cuijpers, & Andersson, 2009; Almlöv et al., 2011; Knaevelsrud & Maercker, 2006; Preschl et al., 2011). However, there are few studies, and results may be biased by small and self-selected samples (Knaevelsrud & Maercker, 2006; Preschl et al., 2011).

Adherence and acceptability

A potential effect in reducing symptoms is an essential attribute of new interventions, but interventions have limited utility if they are not acceptable to patients and are not used in the intended way. Low uptake rates of research trials suggest that there may be significant barriers to commence internet-based treatment (Waller & Gilbody, 2009). Studies show that about 50 % of primary care patients would consider seeking internet-based treatment (Gun,

Titov, & Andrews, 2011; Mohr et al., 2010). However, most patients preferred face-to-face therapy, and only about 10 % would prefer or were definitely interested in internet-based treatment. This shows that there is still work to be done in informing the public about the effectiveness, safety and availability of internet-based interventions.

Various terms have been used to describe study dropout. Attrition or dropout refers to individuals who fail to complete follow-up assessments in accordance with the research protocol (Christensen, Griffiths, & Farrer, 2009). Non-adherence or non-usage refers to participants who withdraw from treatment and therefore, receive less exposure to the treatment material than prescribed in the protocol. Thus, adherence and usage describes to which extent participants have used the intervention under study. In a study of internet-based treatments participants may be non-adherent, but still complete trial assessments, but the opposite is also possible, i.e. that individuals dropout from follow-up assessments, but continue to use the intervention.

Non-adherence to internet-based treatments is a cause of concern. Studies have shown wide variations, but rates of adherence are generally between 50 % and 70 % (Christensen et al., 2009; Kelders et al., 2012; Melville, Casey, & Kavanagh, 2010). Especially high levels of non-adherence, as high as 99 %, have been reported for unguided open access websites (Christensen, Griffiths, Korten, et al., 2004). Again, favourable results have been shown for guided interventions compared to unguided, suggesting that support may reduce non-adherence and dropout from treatment (Cowpertwait & Clarke, 2013; Kelders et al., 2012; D. Richards & Richardson, 2012). In their review, Richards and Richardson (2012) estimated the mean level of dropout to be 74 % and 28 % for unguided and therapist guided interventions, respectively. A meta-analysis suggested that the average percentage of sessions completed for guided internet-based interventions and face-to-face CBT for depression was equivalent, but that a higher proportion of patients completed treatment in face-to-face therapy (Van Ballegooijen et al., 2014). It has been shown that non-completers may experience significant benefits before dropping out of treatment (Newby et al., 2013; Newby et al., 2014). However, there is also evidence indicating a dose-response relationship between usage variables and symptom change (Christensen, Griffiths, Groves, & Korten, 2006; Christensen, Griffiths, Korten, et al., 2004; de Graaf, Huibers, Riper, Gerhards, & Arntz, 2009; Hedman et al., 2014; Hilvert-Bruce, Rossouw, Wong, Sunderland, & Andrews, 2012; Newby et al., 2014). This emphasises the importance of efforts to increase retention by providing support or through other means, such as reminders (Hilvert-Bruce et al., 2012).

Treatment satisfaction is another important aspect of acceptability. Studies indicate that patients completing internet-based treatments are largely satisfied (Cavanagh et al., 2009; Kaltenthaler et al., 2008; Meyer et al., 2009; Moritz, Schilling, Hauschildt, Schroder, & Treszl, 2012; Perini et al., 2009; Waller & Gilbody, 2009). Being able to identify with and apply the material to one's own situation is an important factor increasing perceived helpfulness and motivation to persist with treatment (Bendelin et al., 2011; Gerhards et al., 2011). There are some reports indicating that programs may be too demanding and burdensome for some patients (Andersson et al., 2005), especially for patients with chronic physical or cognitive morbidity causing symptoms of fatigue and poor concentration (Hind et al., 2009; Topolovec-Vranic et al., 2010). The preference or need for support also seems to be a recurring theme in several studies (Bendelin et al., 2011; Gega, Smith, & Reynolds, 2013; Gerhards et al., 2011; Hind et al., 2009). Some participants experience that anonymity facilitates emotional disclosure, whereas others miss face-to-face contact with a therapist (Beattie et al., 2009; Gega et al., 2013; Gerhards et al., 2011). Clearly, programs are perceived differently by participants and may be best suited for individuals who are able and motivated to work independently, and who manage to relate to the material and approach it in a structured and practical way by applying it to experiences in their everyday life (Bendelin et al., 2011; Gerhards et al., 2011).

For whom is internet-based treatment effective?

Despite encouraging results, internet-based treatment is not suitable for all depressed patients, and there is a considerable level of non-response, as indicated by rates of non-response between 50 % and 65 % (Berger et al., 2011; Johansson, Sjöberg, et al., 2012; Perini et al., 2009; Ruwaard et al., 2009; Vernmark et al., 2010). Therefore, the question of for whom this treatment is effective is important to address.

An increasing number of studies are attempting to pinpoint variables that can predict differential response to internet-based treatments (e.g., Donker, Batterham, et al., 2013; Farrer, Griffiths, Christensen, Mackinnon, & Batterham, 2014; Spek, Nyklicek, Cuijpers, & Pop, 2008). The ultimate aim is to inform treatment selection by improving the ability to match specific treatments to specific patient characteristics in order to achieve better outcomes (Simon & Perlis, 2010). So far this research has yielded largely inconclusive results. Some more consistent patterns have been found for depressive severity indicating that high initial severity may be associated with more difficulty achieving remission, whereas response in terms of symptom change may be achieved more readily for these patients, since

higher severity leaves more room for improvement (e.g., Andersson, Bergström, Holländare, Ekselius, & Carlbring, 2004; Button, Wiles, Lewis, Peters, & Kessler, 2012; de Graaf, Hollon, & Huibers, 2010; Spek et al., 2008; Warmerdam, Van Straten, Twisk, & Cuijpers, 2013). The literature on prediction of response to internet-based interventions is discussed more thoroughly in Paper III.

Aims of the thesis

The overall aim of the thesis is to explore the effectiveness of a Web-based self-help program combined with brief face-to-face support for adult primary care patients with mild to moderate depression. The first phase of the project included a review of previous literature on CBT delivered in primary care (Paper I), and a randomised controlled trial (RCT) conducted at the UiT The Arctic University of Norway (Paper II and III). The second phase explored the process of implementation in everyday practice by GPs following an educational course (Paper IV). Specific aims of the papers are described below.

Paper I:
Reviewing the literature on CBT delivered in primary health care: Is the treatment effective?

Paper II:
• Is guided Web-based CBT effective in reducing symptoms of depression and anxiety compared to a waitlist control group?
• Is guided Web-based CBT effective in increasing satisfaction with life and quality of life compared to a waitlist control group?
• Are benefits of the intervention sustained at 6-month follow-up?
• Is the intervention acceptable to participants?

Paper III:
• Can pre-treatment participant characteristics predict response to guided Web-based CBT?

Paper IV:
• Qualitative study exploring aspects perceived by GPs to affect implementation of guided Web-based CBT in routine practice.

Methods

Study Design

The present thesis is based on data from both quantitative and qualitative research. The first phase of the project included a RCT conducted at the UiT The Arctic University of Norway (Paper II and Paper III). The trial compared a treatment condition comprising 6 weeks of Web-based CBT with therapist support to a 6 weeks waitlist for the same treatment. The second phase of the project aimed to evaluate the effect of this treatment protocol compared to treatment as usual when delivered by GPs in routine practice. Due to low recruitment of patients to this trial, the main outcome of this phase was a qualitative interview-study exploring how GPs had implemented the treatment and which aspects were perceived to affect implementation (Paper IV).

Methods were chosen based on their suitability for answering the research questions at hand, and the multiple methods employed in the project supplemented each other by being appropriate for investigating different questions. The design can however, not be considered a mixed-methods design. The qualitative inquiry does to some extent build on the findings from the RCT, but the different methods were used to investigate different questions and not to help us see a topic from multiple sides, and without a specific plan for integrating results to broaden our understanding of the research topic (Greene, 2008; R. B. Johnson, Onwuegbuzie, & Turner, 2007).

Quantitative methods are related to positivist and empiricist traditions emphasising that science should be based on observable data, and that research should be neutral, objective and employing stringent methods so that it may be replicated by other researchers (Hergenhahn, 2001; Kvale & Brinkmann, 2009). Data is numerical, and the aim is to test hypothesis, explain causation, quantify effects and predict events. Therefore, quantitative methods were considered appropriate for answering the research questions of the first phase of the project in which evaluation and prediction of effects in terms of the measurable improvement of symptoms was the main aim.

Qualitative research aims to describe and increase our understanding of various aspects of a phenomenon (Malterud, 2011). The focus is on the experiences, perceptions, thoughts, attitudes, values and relations of human beings. This is investigated through a systematic collection and analysis of text-based material. Data collection may include interviews, observation or written material. Qualitative research may provide new knowledge about the meaning of events, e.g., how an event is perceived by participants, what meaning

participants ascribe to the event, and why participants behave the way they do. This may be useful if the aim is to understand the diversity and nuances of experiences, and if the research field is complex and previous research is scarce. Implementation of online treatments in general practice is largely an undiscovered research field, and therefore our overview of which factors may be important for the GPs was very limited. The ability to ask open-ended questions and to elaborate on their answers to better grasp their experiences with this new treatment model makes the qualitative approach more suitable to explore this research question.

The research protocol was approved by the Regional Committee for Research Ethics in Northern Norway (2011/2163) and the Human Ethics Committee of the Australian National University. The RCT was registered in the Australian New Zealand Clinical Registry (ACTRN12610000257066). In the following sections the methods of the quantitative and qualitative part of the project will be discussed in more detail.

Phase 1: Randomised Controlled Trial (Paper II and III)

Sample

Participants (n = 106) in the RCT were primary care patients with depressive symptomatology. As the trial included face-to-face contact all participants lived in Tromsø or suburban areas. Inclusion criteria were: (1) 18 – 65 years of age, (2) access to the Internet, and (3) a score between 10 and 40 on the Beck Depression Inventory-II (BDI-II), indicating mild to moderate symptoms of depression. In the original protocol the criterion was a BDI-II score between 14 and 29, but this was changed during the 6th month of the study due to insufficient recruitment, and the clinical appraisal that patients with scores above 30 could possibly benefit from the treatment, based on their daily functioning and motivation. In addition, their depression was too mild to assure them other public treatment options. Furthermore, several patients with a BDI-II score below 14 reported a need for treatment. Ethical considerations concerning the withholding of possibly effective treatment from patients with limited access to other treatment options were also influencing this decision. Individuals currently undergoing CBT were excluded, whereas individuals who used antidepressant medication had to be stabilised for one month prior to entering the trial. This interval of medication stabilisation is commonly used in research on internet interventions (e.g., Hedman et al., 2014; Wagner et al., 2014). As the trial aimed to mimic the conditions of general practice, a heterogeneous group of patients with depressive symptoms was included. Comorbidities only restricted inclusion when these conditions required immediate treatment (suicidal ideation,

current psychosis) or were expected to interfere considerably with the treatment of the depressive condition (alcohol or drug use disorders).

Paper II focuses on the total sample of 106 participants. Figure 1 shows the flow of participants through the trial. Paper III merges the data from the treatment phase of both the intervention and control group and examines the subsample of participants who attended at least two sessions (n = 82). This sample excluded participants from the waitlist control group who dropped out while waiting for treatment (n = 7), or who no longer met the inclusion criteria on BDI-II when entering the treatment phase (n = 7), and participants in both groups who attended only one treatment session (n = 7), or were considered outliers (n = 3).

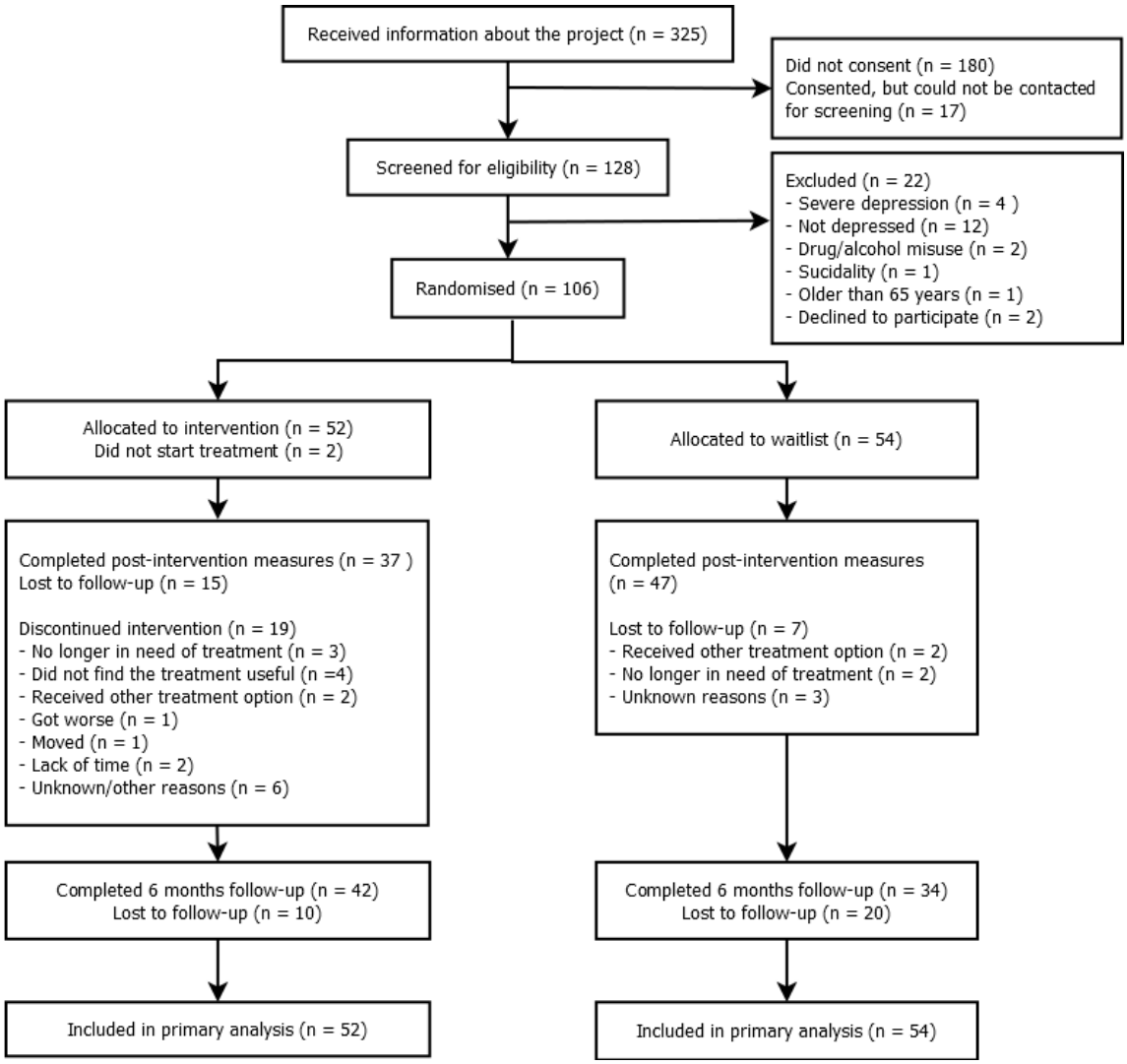

Figure 1. Flow of participants through the trial.

Recruitment

Participants were recruited between October 2010 and October 2012 from GPs, primary care nurses and from waitlists of primary care referrals at two psychiatric outpatient clinics. Two GPs from the research group (Wilhelmsen and Kolstrup) informed local GPs about the study at practice meetings, and two psychologists (Lillevoll and Høifødt) held information meetings with primary care nurses. Written information was also provided. Practitioners were encouraged to give written information about the project to patients appraised to have mild or moderate symptoms of depression. Potentially eligible patients awaiting psychiatric outpatient treatment were identified by clinic staff and received information about the project from the research group by postal mail. Information to patients described the treatment and the purpose of the project, addressed issues of adverse effects and handling of sensitive information, and included an informed consent form. To participate, patients returned this form to the research group. To avoid that patients felt coerced into participating, they were explicitly asked to review information and decide about participation after their appointment with the GP. There was however, anecdotal evidence that some GPs actively recommended participation due to limited access to other psychological treatment.

Intervention

The intervention comprised three components: 1) The Norwegian version of the Web-based program MoodGYM (version 3; Australian National University Centre for Mental Health Research, 2008), b) brief face-to-face therapist support, and c) tailored e-mails between sessions.

The MoodGYM program was originally developed by the Australian National University as a free of charge automated Web intervention delivered to the public as part of the e-hub Web service (Bennett, Reynolds, Christensen, & Griffiths, 2010). MoodGYM consists of 5 self-help modules and 29 exercises. The content is based on CBT and is delivered in a step-by-step format requiring users to complete the previous lesson before the next can be accessed. Tailored feedback and advice is provided based on responses on symptom and other self-report measures. The program was launched in Australia in 2001, and the Norwegian translation was completed in 2006 (Lintvedt, Griffiths, Eisemann, & Waterloo, 2013). The translation was undertaken by the present research group using both expert translators and clinical professionals.

The program was developed to prevent and reduce symptoms of depression and anxiety in adolescents (Calear et al., 2009), but studies have demonstrated its effectiveness in

both adolescent and adult populations (Calear et al., 2009; Christensen, Griffiths, & Jorm, 2004; Farrer et al., 2011; Lintvedt, Griffiths, Sørensen, et al., 2013; Powell et al., 2013; Sethi, Campbell, & Ellis, 2010). The first module introduces the cognitive model and six characters exemplifying distinct cognitive and emotional patterns. These characters are used to illustrate examples throughout the program. The second and third modules elaborate on cognitive distortions and introduce exercises to identify and restructure dysfunctional thinking, as well as behavioural strategies to increase engagement in positive activities. Identification of stressors, stress reduction and relaxation techniques is covered in module 4, and the last module focuses on typical responses to broken relationships and introduces a problem solving technique. Participants in the trial received a trial username and password to enter the site and were instructed to work at home with one module each week. No identifying information on the person was stored by the program.

The present intervention combined the MoodGYM program with brief face-to-face support (15 – 30 minutes). The choice of adding support was based on previous research indicating that this enhances treatment effects (Cowpertwait & Clarke, 2013; Johansson & Andersson, 2012; D. Richards & Richardson, 2012; Spek et al., 2007). Participants met with the same therapist for a screening session, a session introducing the program, five brief supportive consultations focusing on module content, and a concluding session evaluating progress and how the intervention was perceived (see Figure 2). The main elements of the supportive sessions were reinforcement of progress, discussion of key messages from the modules, and helping participants to relate to the material and employ techniques from the program in their daily life. Motivational issues were also addressed. Participants also received reminder e-mails between sessions aiming to further enhance motivation to work with MoodGYM. The e-mails introduced the present module, and some contained brief advice on how to overcome depression.

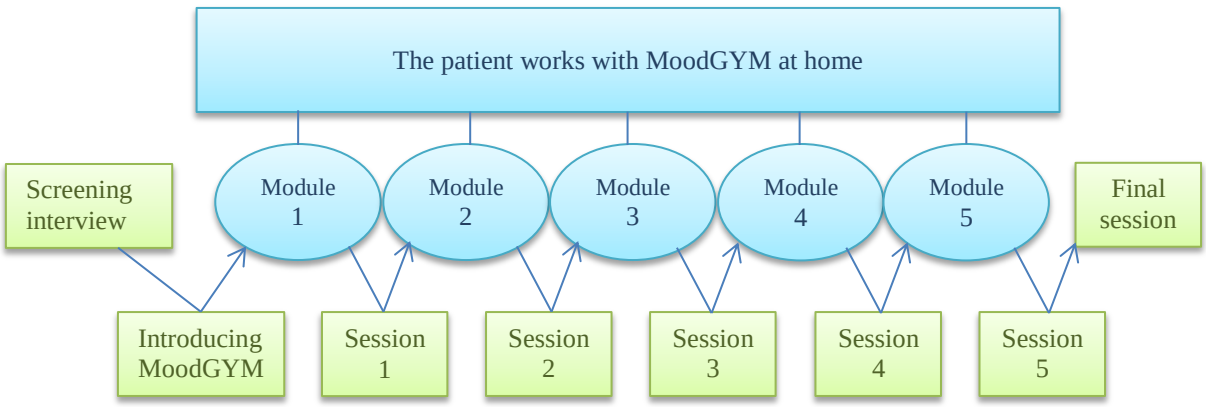

Figure 2. Outline of the intervention.

Even though the intervention was delivered outside the regular health care system, it was considered ethical to share information regarding clinical condition and progress with the patients' GPs who have the responsibility for initiating additional treatment and referring to specialised mental health services if required. Therefore, if participants consented, case summaries were sent to their GPs. Participants in both the intervention and waitlist control group were free to access any treatment during the trial, including antidepressant medication. The therapists in the trial assisted patients being in need of specialised services in getting referred to more extensive treatment.

Procedure

Consenting participants were contacted by the therapists for a screening appointment. Eligible participants were randomised to the intervention or control group. The randomisation procedure is described in detail in Paper II. Randomisation was not concealed and therapists were not blind to group allocation. A research assistant blind to allocation assignment collected the post-tests.

Screening, enrolment and treatment was carried out by two members of the research group (Høifødt and Lillevoll) who are licenced clinical psychologists. Both had basic clinical CBT skills, but less than 2 years of experience from clinical practice and no prior experience with internet-based treatment. The choice of therapists was mainly a pragmatic one. However, it was considered more proper to use less experienced psychologists compared to expert CBT-therapists, as this would increase the generalisability to other groups of less experienced therapists such as GPs. The use of GPs was not feasible due to resource constraints.

Measures

All outcome measures were based on self-report. Assessments of primary and secondary outcomes were completed by all participants at baseline, post-treatment and at 6 months post-treatment. The control group also completed the inventories before entering online treatment (post-waiting). One exception was the measure of treatment satisfaction, which was completed only post-treatment in both groups. The primary outcome measure, BDI-II, was administered before every consultation during the intervention phase.

Primary and secondary outcome measures

The primary outcome measure, BDI-II, is a well-validated 21-item scale measuring depressive severity during the last two weeks (A. T. Beck, Steer, & Brown, 1996). The instrument is

psychometrically sound (Arnau, Meagher, Norris, & Bramson, 2001; A. T. Beck et al., 1996; Dozois, Dobson, & Ahnberg, 1998), and the BDI-II and its forerunner BDI are widely used as outcomes in trials of conventional and internet-based treatments (Jakobsen et al., 2011a, 2011b; D. Richards & Richardson, 2012). Details on the psychometric properties of this and all other outcome measures described in the following sections are reported in more detail in Paper II and III. All questionnaires are enclosed in Appendix I, except the BDI-II and BAI which are protected by copyrights.

The secondary outcome measures comprised an additional measure of depression, measures of anxiety, quality of life and treatment satisfaction. The Hospital Anxiety and Depression Scale (HADS) is a 14-item inventory with two subscales measuring depression and anxiety, respectively (Zigmond & Snaith, 1983). The scale was originally developed for use in non-psychiatric hospital clinics. Therefore, all symptoms also commonly related to physical disorders (e.g., dizziness) were eliminated. This scale was chosen as a secondary outcome as it is widely accessible to Norwegian GPs through the electronic medical handbook (Norsk Elektronisk Legehåndbok; Norsk Helseinformatikk 2014), and it would therefore be a viable outcome measure for the second phase evaluation in general practice.

Anxiety was an important secondary outcome for two reasons. Firstly, because depression and anxiety often co-occur, it was likely that a substantial proportion of trial participants would have anxious symptoms of elevated or clinical levels (Kessler et al., 2005). Secondly, the MoodGYM program was developed to decrease symptoms of both depression and anxiety (Calear et al., 2009). Two complementary measures of anxiety severity during the last week were used: The Beck Anxiety Inventory (BAI; A. T. Beck & Steer, 1993) and the anxiety subscale of the HADS. The BAI is a 21-item measure of anxiety severity focusing mainly on neurophysiological, autonomic and panic symptoms (A. T. Beck & Steer, 1993). The HADS anxiety subscale, on the other hand, focuses mainly on more subjective aspects of anxiety such as worry, nervousness and not being able to relax.

Two measures of quality of life (Satisfaction With Life Scale and EuroQol 5-dimension Self-Report Questionnaire) were included to allow for evaluation of treatment effects on life satisfaction and functional improvement. The Satisfaction with Life Scale (SWLS) measures global life satisfaction evaluated according to the individual's own criteria, and it does so without tapping into related constructs such as positive or negative affect (Diener, Emmons, Larsen, & Griffin, 1985). Respondents are presented with five statements and asked to rate to what degree they agree with these. The EuroQol 5-Dimension Self-Report Questionnaire (EQ-5D) evaluates health related quality of life by measuring level of

functioning for the dimensions mobility, self-care, usual activities, pain/discomfort and anxiety/depression (EuroQol Group, 2013). These two scales extend the perspective on improvement beyond mere symptomatic improvement. Both constructs pertain to the clinical implementation and practicability of the intervention, and functional improvement is critical to the evaluation of cost-utility (So et al., 2013).

Acceptability of the intervention was evaluated by examining (1) rates of attrition and reasons for dropout, (2) adherence to the intervention, and (3) satisfaction with treatment. Adherence to the full intervention was defined as completing MoodGYM and attending at least 7 sessions. Use of MoodGYM was registered online, and module completion was expressed by a number between 0 and 4, where 0 indicates no use and 4 indicates completion. Treatment satisfaction was assessed using nine questions where respondents rated their satisfaction with various aspects of the intervention. The questionnaire was developed for the present study, but the content was influenced by patient satisfaction questionnaires used in other studies (Cavanagh et al., 2009; A. Garratt et al., 2006; Nasjonalt kunnskapssenter for helsetjenesten, 2007). The questions are described in detail in Paper II.

Screening measures

The M.I.N.I. Neuropsychiatric Interview was used to screen for current psychosis and suicidal ideation, and to describe the sample, e.g., the proportion of participants having a diagnosis of major depressive episode and rates of comorbidity. The M.I.N.I. is a structured diagnostic interview showing good sensitivity and specificity (Sheehan et al., 1998). Alcohol and drug use disorders were screened for by means of The Alcohol Use Disorders Identification Test (AUDIT; Saunders, Aasland, Babor, De La Fuente, & Grant, 1993) and The Drug Use Disorders Identification Test (DUDIT; Berman, Bergman, Palmstierna, & Schlyter, 2005), respectively. These instruments measure alcohol and drug use in the last 12 months, as well as alcohol- and drug- related problems. Further details on the screening process and the measures are given in Paper II.

Predictor variable.

In Paper III several variables were explored as possible predictors of treatment response as measured with BDI-II. Variables were predominately chosen on the basis of previous research, but some measures were included for exploratory purposes.

Demographic variables included gender, age, marital status, and employment status collected during the screening interview. Severity variables included pre-treatment measures

of severity of depressive and anxious symptoms (HADS, BAI), quality of life (EQ-5D), satisfaction with life (SWLS), and previous treatment (psychotherapy or medication), as well as depression and anxiety diagnosis, number of depressive episodes, and alcohol use (AUDIT) assessed at screening. The cognitive variables dysfunctional thinking assessed with The Warpy Thoughts Quiz in the MoodGYM program and general self-efficacy (The General Self-Efficacy Scale) were also explored as potential predictors of response. In addition, we investigated the predictive effect of module completion (collected online), treatment expectancy, attitudes towards using an internet-based program and motivation. The three latter variables were assessed with single items developed for the present study. All measures and their psychometric properties are described in more detail in Paper III.

Analysing treatment effects (Paper II)

Randomised controlled trials are widely accepted as the gold standard for studying the effect of treatments (Moher et al., 2010). The randomisation of participants ensures that selection effects are not confused with intervention effects, and, thus, one can claim an unbiased comparison of the effects in the chosen conditions (Kraemer, Wilson, Fairburn, & Agras, 2002; Lachin, 2000). Another criterion for claiming that a study is unbiased is that outcome measures are collected in an unbiased way for all participants. This includes proper blinding of treatment allocation to participants, clinicians and outcome assessors, to the extent that this is possible.

Even when randomisation and blinding is rigorously implemented, comparisons may not be truly unbiased if there is missing data (Lachin, 2000). Analysing data solely from participants receiving the prescribed treatment and completing the planned assessments may introduce bias since one cannot claim that this subset of participants is representative for the full sample, and thus, the benefits of randomisation is lost (Y. J. Lee, Ellenberg, Hirtz, & Nelson, 1991). Therefore, in order to obtain an unbiased comparison, outcomes from all participants initially assigned to receive treatment should be analysed irrespective of treatment adherence or incomplete follow-up data (Lachin, 2000; Moher et al., 2010). This principle is referred to as intention-to-treat (ITT).

In the present trial (Paper II) results on the BDI-II and BAI were analysed using ITT analysis. Participants were analysed in the group they were randomised to, irrespective of treatment adherence. A modified ITT analysis was performed for the remaining secondary measures due to missing data at pre-test. In this analysis all participants completing the measure at least once were included.

Mixed-effects models

As in most studies the present trial suffered from dropout (71 % and 87 % completed post-intervention measures in the intervention and waitlist control group, respectively). When using methods such as analysis of covariance (ANCOVA) and repeated-measures analysis of variance (ANOVA) cases with missing data must be left out or missing values must be imputed using last observation carried forward (LOCF) in which the last observation from the participant is used for all subsequent missing observations, or through other imputation methods (Gueorguieva & Krystal, 2004). Constant value imputation methods, like LOCF, lead to high risk for estimation bias (Gueorguieva & Krystal, 2004; Lachin, 2000). In mixed-effects models, also called multilevel models, all available data for all participants are used, and correlations between repeated measures from the same individual are accounted for (Twisk, 2006). These correlations allow missing data to be partially recovered and, therefore, imputation of missing values is unnecessary (Schafer & Graham, 2002). In the present trial, all primary analyses of effects used linear mixed-models analyses with the restricted maximum likelihood estimation (REML) procedure and an unstructured covariance matrix. Maximum likelihood estimation is considered an effective method for using all available data and are therefore, recommended for use in longitudinal models with missing data (Christensen et al., 2009; Gueorguieva & Krystal, 2004; Mallinckrodt et al., 2003; Schafer & Graham, 2002).

For the analysis of BDI-II during the treatment phase, random intercepts across participants were estimated, and BDI-IIs from every treatment session were included for the intervention group. Mixed-effects models include both fixed and random effects. The fixed effects are similar to the regression parameters in a regular multiple regression, and refer to the effect of treatment on the average intercept (baseline level) and slope (rate of change; Chakraborty & Gu, 2009). The random intercept represents the variance over the individual intercepts (Twisk, 2006). This means that in the current analysis between-person variability was assumed for the intercepts, but not for the slopes. Time was treated as a continuous variable (weeks from baseline), but because the control group only completed measures pre- and post-treatment only linear time trends could be estimated.

For the secondary measures and for all analyses including 6-month follow-up data, repeated measures linear mixed-models analyses were performed with occasion (baseline, post-test, 6-month follow-up) as the repeated factor.

Missing data

The mixed-effects models can effectively deal with missing data, but assume that data are missing at random (Twisk, 2006). Missing data can be classified in accordance with the mechanism leading to missingness (Little & Rubin, 1987). The term *missing completely at random* (MCAR) refers to situations in which there is no relationship between the missing value and any observed or unobserved variables of interest. This is seldom the case. When data is defined as *missing at random* (MAR), missingness may depend on other observed variables such as gender or other demographic variables, or it may depend on responses on previous measurement occasions. However, missingness cannot depend on the unseen responses themselves (Little & Rubin, 1987). This is also called ignorable or non-informative nonresponse (Schafer & Graham, 2002). An example may be when a depression score is missing due to the participant being too depressed to show up. When this is the case, data is defined as *missing not at random* (MNAR). This is also called non-ignorable or informative nonresponse (Schafer & Graham, 2002). Methods assuming MAR also hold under MCAR, but may be biased if data is MNAR (Mallinckrodt et al., 2003).

Whenever missingness is not controlled by the researchers one may only assume MAR, as it is difficult and often impossible to clarify why data is missing (Gueorguieva & Krystal, 2004; Schafer & Graham, 2002). It has been suggested that in practice deviations from MAR are seldom large enough to substantially bias results from MAR-based analysis (L. M. Collins, Schafer, & Kam, 2001; Schafer & Graham, 2002). However, one cannot completely rule out the possibility of non-random patterns of missing data. There are approaches that attempt to account for MNAR data, and such approaches may be beneficially used within a sensitivity analysis framework to assess whether results obtained with MAR methods such as mixed-effects models, are valid and robust (Mallinckrodt et al., 2003). One such method employs pattern-mixture models in which participants are divided into groups based on their patterns of missing data (Hedeker & Gibbons, 1997). Analyses can then examine to which extent these patterns influence the outcome of interest and provide estimates averaging across different patterns of missingness. Augmenting the mixed-effects models with analyses not requiring an ignorable missing data mechanism would have been preferable. However, this was not done in the present trial due to the statistical complexity of such methods.

The size and significance of effects

Whether a treatment is effective or not is a research question that cannot be answered properly with yes or no. Therefore, besides p-values there is a need for reporting estimates describing the size of the difference in treatment effects between groups (effect size; Vickers, 2005; Wilkinson, 1999). This eases appropriate interpretation of trial results in comparison with previously reported effects. In the present study the size of treatment effects was expressed as Cohen's *d* effect sizes. Effect sizes were estimated for the between-group difference in effect and for within-group changes during treatment. Calculations were based on change scores derived from the estimated means or β-coefficients (BDI-II) from the mixed-effects analysis and pooled standard deviations (further details are reported in Paper II; Silfvernagel et al., 2012). A Cohen's *d* of 0.2 was considered a small effect, 0.5 a medium effect and 0.8 or more large effects (J. Cohen, 1988). Ideally, a confidence interval displaying the range of uncertainty for the true treatment effect should have been included, but this was not done due to the complexity of estimation.

A statistically significant treatment effect bears little importance unless the treatment actually makes a difference in the lives of patients. Clinical significance refers to the practical relevance of changes resulting from treatment (Jacobson & Truax, 1991). Jacobson and Truax (1991) developed a statistical approach to classify the significance of changes during treatment. One may assume that patients entering treatment will belong to a dysfunctional population, and the goal of treatment is to bring about changes so that patients are part of the normal population upon termination of treatment (recovery). By defining cutoff points for symptom measures distinguishing dysfunctional and functional populations, the post-treatment functioning of patients can be classified. However, these populations often overlap, and a change from just above cutoff to just below may not be statistically reliable. Therefore, Jacobson and Truax (1991) also proposed a reliable change index which defines criteria for determining whether changes accomplished during treatment represent actual changes or merely fluctuations. Using this approach patients can be classified as deteriorated (reliable negative change), unchanged (no reliable change), improved (reliable positive change, but end-point symptom level not within normal range) and recovered (combination of reliable improvement and end-point symptom level within normal range). In the present study clinically significant change on the BDI-II was assessed using the criteria for reliable change and cutoff points developed for the BDI by Seggar, Lambert and Hansen (2002), based on the definition by Jacobson and Truax (1991). Further details are reported in Paper II.

Prediction of treatment response using Bayesian analysis (Paper III)

For analysing predictors of treatment response in Paper III Bayesian statistics were used. The next section gives an overview of this approach and its advantages compared to conventional statistics.

Bayesian statistics is an approach to statistical inference that is fundamentally different from the standard approach of null hypothesis significance testing which is most commonly used in psychological research (M. D. Lee & Wagenmakers, 2005). Bayesian analysis is based on probability theory and takes its name from Thomas Bayes (1702-1761), a mathematician and minister, who postulated the Bayes' theorem which is a simple rule that relates conditional probabilities (Kruschke, 2010). A conditional probability is the probability of an event given that we know another event to be true. Observing data in a study provides us with knowledge about the conditional probability of the data given the underlying model structure and parameter values. What makes the Bayes' theorem so useful in the context of statistical inference is that this rule can be used to convert what we know about the probability of the data given the model to determine the probability of the model given the observed data. In other words, we gain knowledge about which parameter values are most likely to have generated our data given that the model has been correctly formulated, and this is often the very question researchers set out to answer. Through model comparison, different models can be compared to determine which model fits the data best, and whether the best model accounts well for the data can be assessed by performing posterior predictive checks where the posterior predictive distribution is compared to the actual data (Kruschke, 2010).

The goal of standard statistics is to determine if the null hypothesis can be rejected, and this is accomplished by determining the probability of the observed data given that the null hypothesis is true (Kruschke, 2010). If the observed data is sufficiently improbable (usually less than 5 % probability) given that the null hypothesis is true, one can reject the null hypothesis. However, one cannot from this infer the probability of the null given the observed data, which means that one cannot infer to which degree the results provide nonsupport for the null hypothesis or support for another hypothesis. Thus, standard statistics only indirectly answers questions regarding which hypothesis is supported by the data.

The standard approach has received fierce criticism (e.g., Dienes, 2011). Some of the main points revolve around the issue that different results can come from the same data depending on the intentions of the researcher (Kruschke, 2010). Some problems have received much attention, namely the fact that conclusions may be influenced by when the researcher decides to stop collecting data (the stopping rule), whether hypotheses were formulated before

or after inspecting the data (planned versus post hoc comparisons), and the number of hypotheses the researcher decides to investigate (multiple comparisons; Dienes, 2011; Kruschke, 2010). None of these problems apply to Bayesian statistics where conclusions are contingent solely upon the data relevant for the research question of interest. As the aim of Bayesian analysis is not to test the statistical significance of effects, the method relies much less on point estimates and on an arbitrary choice of significance levels.

In Bayesian inference what is known about variables, as well as the remaining uncertainty of the data is represented through probability distributions in which a probability is assigned for each possible outcome of the variable (Kruschke, 2010; M. D. Lee & Wagenmakers, 2005). A characteristic feature in Bayesian analysis is that prior knowledge about a phenomenon is incorporated into the analysis through the prior probability distribution. The prior is explicitly defined and accessible to be debated by peers (Kruschke, 2010). As data is collected this prior distribution is updated in accordance with Bayes' theorem to yield the posterior distribution from which conclusions about parameter estimation and prediction can be drawn.

Instead of reporting p-values, Bayesian methods report the results of an analysis in terms of probabilities, odds-ratios and Bayes factors. Odds ratios are ratios of probabilities and give the relative probability of one event with respect to another. For example, if the odds ratio of event A relative to B is 5, then event A is 5 times more likely to be true compared to event B. The Bayes factor compares the evidence for one model or hypothesis relative to another model or hypothesis (M. D. Lee & Wagenmakers, 2005; Wagenmakers & Grünwald, 2006). The neat thing about this is that it tells us about the plausibility of a model relative to another, and it also makes it possible to quantify the evidence supporting the null hypothesis and not just determine if it has been rejected or not (Dienes, 2011). In addition, research shows that Bayes factors give more conservative estimates of effects than p-values and may, therefore, prevent overestimation of effects (Wetzels et al., 2011).

In addition to these general advantages of Bayesian methods, these methods were considered to be particularly suitable for the analysis in Paper III because Bayesian modeling enables the use of very flexible methods of analysis. The posterior distribution can be readily transformed into easily interpretable quantities, and the uncertainty inherent to the analysis is propagated and available at each level of analysis. Bayesian hierarchical modeling allows the design of custom models that are appropriate for the data without relying on approximations as is necessary in standard statistics. Finally, the ability to quantify the evidence for the null-hypothesis was considered to be a particularly desirable feature when investigating the

potential impact of predictor variables on treatment response. This allows us to determine both which variables that do impact on response and which do not, and the latter may give just as interesting information as the former.

Phase 2: Qualitative Study of GPs' Experiences with Implementation (Paper IV)

Epistemology, methodology and methods are fundamental concepts in qualitative research (S. M. Carter & Little, 2007). Epistemology is the theory of knowledge, what is knowledge and how can we gain it (Kvale & Brinkmann, 2009). Kvale and Brinkmann (2009) illustrate two opposite epistemological positions and approaches to interview-based research, using the metaphor of the miner and the traveller. The miner sees knowledge as precious metals that can be uncovered through the interview. In this view the experiences of the interviewee and essential meanings exist in their own right, and by asking open-ended questions the interviewer may uncover this knowledge without affecting its content. This can be considered an interpretivist view (Schwandt, 2000). The traveller on the other hand engages in conversations with people he meets along the way. Within these conversations knowledge is socially produced and reproduced (Kvale & Brinkmann, 2009). In this view knowledge can neither be found in the world outside nor within a person, but only in the relation between individuals. Furthermore, we are all situated within a historical and sociocultural context, and all knowledge is constructed within this framework (Schwandt, 2000). This is in line with a social constructivist position.

Carter and Little (2007) has proposed a model describing the relationship between epistemology, methodology and methods and argues that good qualitative research is research were all three elements are clarified and internally coherent. Methodology is not the methods themselves, but is the overall strategies for approaching qualitative research. It can be thought of as the justification of the methods, which are the research actions, i.e. the practical activities of the research project such as sampling, data collection, analysis and reporting. As illustrated by the metaphor, the epistemological position shapes the choice of methodology and influences the relationship between the researcher and the participants. Furthermore, methodology guides the choice of research questions and design. However, this relationship is not unidirectional, and objectives, research questions and design also influence the choice of methodology. For example, in a phenomenological methodology one would endeavour to uncover the essence or meaning of participants' experiences. This guides the choice of objectives, research questions and design. However, if exploring individual experiences were not the desired objective, this would guide us away from phenomenology and towards another

methodology. For instance, if the aim of the project was to develop theories, this may guide us towards a grounded theory methodology. Methodology may also encourage or discourage the use of existing theories during the research process, e.g., during analysis and interpretation of data. This illustrates that the qualitative research process is not linear, but a complex interplay between epistemology, methodology, methods, existing theory and the objectives, research questions and design.

Objectives and research questions

The objectives and research questions of the study were shaped by the context in which it took place. Following the RCT we wanted to disseminate knowledge about the treatment model combining MoodGYM and brief face-to-face follow-ups to GPs to encourage implementation of this treatment in their regular practice. A 3-day educational course on CBT in general practice was developed and delivered in spring 2011 by a GP (Kolstrup) and two psychologists (Lillevoll and Høifødt) from the research group. All Norwegian GPs were invited to participate, but most participants came from the northern part of Norway. The course included: (1) lectures about the principles of CBT, (2) practical training in using CBT techniques, (3) a presentation of the MoodGYM program and a group-session with focus on getting familiarised with program content, (4) presentation of the manual for follow-ups, and (5) a patient telling about his experiences with using the program. The manual for follow-ups was described using practical examples, and this manual and other supplemental material to aid the GPs in delivering CBT and MoodGYM was supplied online. Participants attending the course were advised to introduce and recommend MoodGYM to patients with depressive symptomatology and to provide motivational biweekly follow-up sessions similar in structure and content to the guidance provided in the RCT.

All GPs from the course were invited to participate in a trial to evaluate the effectiveness of the treatment protocol compared to usual treatment in general practice. All GPs working in general practice agreed to this. However, the trial was stopped because of severe problems with patient recruitment. These experiences led to our interest in exploring further how GPs had managed to implement the treatment model and which aspects they perceived to affect their implementation.

Sample

The study included a sample of 11 GPs from northern Norway. Nine of the included GPs had taken part in the educational course. In addition, two GPs who had attended a 3-hour

presentation of MoodGYM given by one of the course attendees, were included for comparative purposes. The participants were both male and female, ages ranged from 33 to 58 years, and years of experience as GPs ranged from 3 to 28 years. The sample was purposive, which means that we aimed to include a sample of individuals with a potential for giving both varying perspectives and nuanced information about the question under study (Malterud, 2011). Therefore it was important to include GPs who had knowledge of the MoodGYM program, and it was preferable to include both men and women, GPs of various ages and with varying levels of experience from general practice. More women attended the course and accordingly, the sample included more women than men. Including more male GPs may have elucidated other aspects affecting implementation. In addition, the sample was self-selected. All GPs had voluntarily attended the course. This may introduce a selection bias, as the GPs in our sample may have been more interested in mental health, CBT and the use of online interventions compared to the average GP. These aspects must be taken into account when judging the transferability of the results to contexts beyond the specific context of the study.

Design, interviews and procedure

When aiming to explore GPs' experiences with implementing an internet-based treatment in their practice, one could attempt to quantify knowledge by conducting a survey. However, there is little previous research to guide the development of a questionnaire. Not knowing what experiences and aspects that may be important to the GPs makes it difficult to choose the right response alternatives, and we would risk losing important information.
We therefore considered the subject more suitable for a qualitative study compared to a quantitative survey. However, also within qualitative research there are several different approaches (Malterud, 2011). Observation can give direct information about events, e.g., how did the GPs actually use MoodGYM in their consultations with patients. However, observation would have provided limited knowledge about the GPs' thoughts and reflections about using the new treatment. This knowledge may best be captured by interviewing GPs individually or through focus group interviews (Kvale & Brinkmann, 2009). Interviews give us indirect information about events, but more direct descriptions of the experiences of participants. In focus group interviews topics are discussed openly in a group and different opinions and points of view may be forwarded. However, more in-depth information about each participant's experiences may be lost. This method could have been useful to explore our research question, but as not all GPs lived in the same area and the course did not include follow-up meetings, it was impractical in the current context. In addition, our main interest

was to get a more in-depth account of the experiences and perceptions of participants. Therefore, one-to-one semi-structured in-depth interviews were conducted.

An interview guide (see Appendix II) was developed by the research group to elicit information about (1) the GPs' general view on working with depressed patients, (2) motivational aspects for learning CBT, (3) experiences from implementing MoodGYM in their routine practice including facilitative factors and barriers, and (4) implications of using a Web-based program on patient-doctor-interaction and consultation quality. The guide gave structure to the interviews and ensured that important topics were covered by suggesting specific questions (Kvale & Brinkmann, 2009). However, the guide was not intended to impose strict structure upon the conversation, and we aimed to conduct the interviews as a dialogue guided by open-ended questions. This was done to evoke descriptions of situations and experiences from daily practice, and thereby aiming to reach an understanding reflecting the GPs' perceptions and attitudes. Consistent with Kvale and Brinkmann's (2009) recommendations the main emphasis was on descriptive questions, e.g., questions starting with *what* or *how*, rather that questions about *why*. This elicits more spontaneous descriptions from participants, and overly intellectual speculations about *why* are avoided. As we gained new insight about the topic throughout the data collection, the interview guide was revised to ensure that relevant topics would be covered in subsequent interviews.

Interviews were conducted by two female interviewers (Wilhelmsen and Høifødt). Individual interviews lasted between 33 and 85 minutes, and GPs could choose to be interviewed in their office, at home or at the UiT The Arctic University of Norway. Both time and location were flexible to make it fit with the GPs' schedules. All interviews were audio-recorded and transcribed by the interviewers.

The influence of the researcher

The validity of qualitative research has been questioned by proponents of quantitative sciences who see knowledge generated by means of interviews as subjective (Kvale & Brinkmann, 2009; Malterud, 2011). Qualitative researchers acknowledge that the investigator affects all parts of the research process (Malterud, 2001). The researcher's background affects which questions that are being investigated, which methods are employed, the communication with research participants, which follow-up questions are asked, transcription, analysis, interpretation and reporting of results. However, as Malterud (2001) argues, objectivity and validity of results are ensured by a transparent research process and by acknowledging the researcher's inherent bias. In this way bias is not eliminated, but is accounted for. Hence, the

researcher's preunderstanding and preconceptions must be shared openly. The researcher must also actively seek knowledge that contradicts previous assumptions, and question the process and results of the research (Malterud, 2011). This attitude is referred to as reflexivity.

Good knowledge of the research domain is crucial for conducting a good interview, e.g., by being able to focus on relevant and important topics. However, preformed ideas of the researchers may introduce bias. In the present study, the interviews were conducted by two female health workers (Høifødt and Wilhelmsen). Both were PhD-students, and Wilhelmsen also worked part-time as a GP. Both had been working with research on online interventions for some years and had read a substantial amount of literature supporting the effect of (online) self-help for depression and other mental disorders.

My professional background is in clinical psychology. I finished my studies and training as a psychologist in 2009 and commenced my PhD-studies the same year. My interest in community psychology, prevention and treatment of mild psychological conditions in primary care made me apply for a PhD-position in the current project. My background at the time of the interviews included good knowledge about depression, CBT and online interventions, including MoodGYM. I had also written a review supporting the use of online CBT in primary care. I was a therapist in the RCT, and together with a colleague (Lillevoll) I presented MoodGYM and the manual for follow-ups at the educational course. Hence, I had thorough experience with implementing the intervention, although, in a very different setting than general practice. My assumptions regarding the treatment model were somewhat ambivalent. Reading the research literature and analysing the quantitative data from the RCT gave me a positive belief in the usefulness of the treatment. However, as a therapist in the RCT I had also received negative feedback from participants about various aspects of the program, and this made me somewhat half-hearted with regard to the program.

As a researcher I also bring attitudes into the interaction with participants. Such judgements, positive or negative, may be referred to as prejudices (J. Clark, 2008). Several attitudes may be mentioned, but I will focus on my attitudes towards GPs. I believe my attitudes towards physicians are generally positive. Both my parents are physicians, as are several other family members, colleagues and friends. I had read about the inadequate treatment of depression and the time pressure in general practice and I expected the GPs to appreciate that patients worked at home with the program, and that the role of the GP could be more of a motivator than a therapist. I perceived the GPs attending the course to be interested, engaged and enthusiastic about treating patients. I also value my personal GP for being competent, attentive and straightforward in his communication.

My involvement as a lecturer at the course may have introduced bias by swaying participants towards expressing more positive attitudes towards the treatment model. We tried to avoid this by explicitly stating that our role and intention was not to advocate the program or the treatment model, but that we wanted to hear about any experiences they had with using it. Personally I aimed to go into the conversations with an intention to understand the perspective of the other individual. I tried to keep an open and curious attitude and to convey this to participants by being attentive and interested, e.g., leaning forward, nodding, and checking my understanding by reflecting it back to them. I was new to conducting qualitative interviews, but had experience from semi-structured interviews and exploring the perspectives of patients through my training and clinical work as a psychologist. My interviews were longer than those of the other researcher (Wilhelmsen). As she was a GP, I may have needed more time to gain knowledge that was taken for granted in the meeting between GPs. However, the content of the interviews were quite similar. Another likely explanation for the difference in interview length is my lack of experience with qualitative interviews and that I rephrased questions more often to be sure that I had not missed out on important information.

Exploring the GPs' experiences

Our aim was to explore the GPs' experiences with internet-based CBT and all aspects perceived by them to have influenced the implementation process. We were interested in exploring their lived experiences, and this refers to the experiences of daily life within which the meaning of many phenomena is taken for granted without further reflection (Lindseth & Norberg, 2004). A simple example may be our experience of a spoon. In our everyday life we know about and use spoons, but in our "natural attitude" we do not reflect on what the meaning of a spoon is or what makes a spoon a spoon. In the interviews we aimed to investigate these meanings that are taken for granted.

In the context of this study we were mainly interested in experiences from the professional life of the GPs. However, the aim was still to explore the meanings taken for granted with regard to their choices and actions, e.g., we were not only interested in accounts of how GPs had used the program, but also in stories reflecting the meanings of these experiences. We regarded the GPs as interpretative beings and were also interested in how they interpreted their experiences (Schwandt, 2000).

To be able to explore experiences and their meaning, one must aim to enter the conversation with a non-judgemental attitude, i.e. to shift away from the natural attitude where meanings are taken for granted and towards a more open attitude in which one refrains

from making factual judgements (Lindseth & Norberg, 2004). We regarded the reality of the participants, their thoughts and experiences, as valid knowledge. However, we acknowledged that the stories of the participants may to some extent be different depending on the interviewer or other contextual factors. In addition, the researcher takes active part both during the interviews, as well as in transcribing, analysing and interpreting the material, and this interpretation can never be isolated from our preunderstanding (Schwandt, 2000). In this sense our position was in between the positions of the interpretivist and the social constructivist.

Analysis

The transcribed interviews were subjected to a thematic analysis. Thematic analysis is useful for identifying patterns of meanings across qualitative data and can be used across a variety of theoretical and epistemological approaches (Braun & Clarke, 2006). This method was considered appropriate as the aim was to search in a straightforward way for patterns across the GPs' stories about their professional experiences with MoodGYM and their thoughts about the subject and not to understand the essence of specific complex phenomena. As our intention was to explore implementation as experienced by the GPs, an inductive approach was used. This means that the coding process is data-driven, and one does not attempt to fit data into a specific coding framework. The analysis was conducted by Wilhelmsen, and themes were validated and discussed throughout the process with another GP (Kolstrup) and an experienced qualitative researcher (Risør). The identification of themes was achieved by working in a stepwise manner. However, as recommended by Braun and Clarke (2006) this was not done as a linear process, but in a process of constantly moving back and forth between the data and potential themes.

The first step involved transcribing the interviews and repeated readings of all transcripts to get familiarised with the material and get an overall impression. The material is read actively, and the researcher starts to search for patterns, but without coding.

The second phase involved initial coding across the entire dataset for extracts that could form a basis for repeated patterns of meaning. Coding was done at the semantic level. This means that focus was on the explicit meanings of the data. Semantic coding was chosen since we were interested in describing the explicit experiences and thoughts of the participants and not in interpreting underlying ideas or assumptions beyond what was being said. Thus, events, thoughts and actions were coded as themes based on their ability to capture something important in relation to the overall research question.

During the third phase codes were sorted into potential overarching themes. Themes were further refined during the fourth phase of analysis. This was approached at two levels. First, the coded extracts of all themes were reviewed to investigate if the themes were internally coherent. The aim was to develop themes that were meaningfully coherent internally, clearly distinct from each other, and that had explanatory power. Second, the relation of the themes to the entire data set was evaluated to ensure that the themes captured the meanings found in the interviews.

The fifth phase included defining and naming themes in terms of scope, content and relation to the overall "story" of the data. This means to identify the "essence" of each theme, as well as the overall "essence" of what the data is about. This process was aided by using maps for visual representations. A storyline starting with the GPs initial motivation to attend the educational course and progressing to how they applied or attempted to apply internet-based CBT in their regular practice was identified. Themes were also interpreted in relation to The Normalization Process Theory (NPT; May & Finch, 2009; Murray et al., 2010). This theory is described in further detail below.

The sixth and last phase included writing the report with the aim of giving a coherent and interesting account of the findings including illustrative quotations. The implications of the results were further interpreted in relation to existing literature.

Existing theory

There exist several theories related to implementing new health care practices (Grol & Wensing, 2004; Meyers, Durlak, & Wandersman, 2012; Proctor et al., 2009). The NPT provides a framework for analysing mechanisms involved in implementation of complex interventions in regular practice (May & Finch, 2009; Murray et al., 2010). The theory can be used as a tool to understand how new practices can become adopted, integrated and eventually routinised (normalised) in regular practice. As it provides a suitable conceptual framework for understanding qualitative data (Murray et al., 2010), this theory was used during the present analysis to sensitise the researchers to specific elements suggested as important during implementation.

The theory identifies factors hindering or promoting uptake and continued incorporation of new interventions in routine practice (May & Finch, 2009; Murray et al., 2010). It defines four types of "work" that in interplay constitutes the process of implementation. (1) Coherence refers to how participants make meaning or sense of the intervention. This includes a clear sense of what the intervention is and how it is different

from the existing practice, as well as perceived purpose and benefit of the new intervention. (2) Cognitive participation defines the commitment and engagement by participants. This refers to the work of "buying in" to the new practice, perceive it as a good idea and work towards getting involved in it, e.g., enrolment in training. (3) Collective action refers to how a practice is operationalised and efforts to use the intervention in practice. This includes efforts to make the new practice fit with existing practices, e.g., within the doctor-patient relationship, in relation to collaboration with other professional groups, and in relation to organisational structures. (4) Reflexive monitoring focuses on ongoing formal or informal monitoring influencing the understanding and appraisal of the value and outcome of the new intervention. A growing understanding of the utility or lack of utility of the new practice will then feed back into the conception of coherence and whether participants find the practice meaningful. Using these concepts made it possible to evaluate which "work" had or had not been done by GPs in the process of implementing MoodGYM in their daily practice. In this sense one can say that after analysing patterns of meaning across data in an inductive way, the findings were analysed deductively with regard to how they fit with relation to the theoretical framework of NPT.

Summary of Papers

Paper I

Høifødt, R.S., Strøm, C., Kolstrup, N., Eisemann, M. & Waterloo, K. (2011). Effectiveness of cognitive behavioural therapy in primary health care: A review. *Family Practice*, 28, 489-504. doi: 10.1093/fampra/cmr017

The purpose of this paper was to review existing research on the effectiveness of CBT for depression and anxiety disorders when delivered in primary health care. The review was selective as it included only studies where CBT was delivered or supported by primary care therapists without extensive specialist training in delivering structured psychological treatments.

Seventeen studies were identified by searching Medline (PubMed) databases, PsychInfo, ISI Web and Google. Eight studies focused on computerised or internet-based CBT, and results indicated that such treatments may be more effective than treatment as usual for mild to moderate depression and anxiety, but not for more severe depression. Four studies using written self-help material found that this treatment was effective in reducing symptoms of depression and anxiety, but did not outperform treatment as usual. Results from five randomised controlled trials indicated that training primary care therapists to deliver CBT face-to-face did not generally enhance treatment effects relative to treatment as usual. Although, face-to-face treatment may be effective when delivered by highly trained primary care therapists under supervision, it may be infeasible for most therapists due to the time and engagement needed to acquire and apply new skills.

The review concludes that computerised or internet-based CBT may be recommended as an alternative or supplement to pharmacological treatment for mild to moderate depression or anxiety.

Paper II

Høifødt, R.S., Lillevoll, K.R., Griffiths, K.M., Wilsgaard, T., Eisemann, M., Waterloo, K., & Kolstrup, N. (2013). The clinical effectiveness of Web-based cognitive behavioral therapy with face-to-face therapist support for depressed primary care patients: Randomized controlled trial. *Journal of Medical Internet Research, 15*(8), e153. doi: 10.2196/jmir.2714

Paper II aimed to evaluate the effectiveness and acceptability of an intervention combining the MoodGYM program and brief face-to-face support from a psychologist for primary care patients with mild to moderate depression.

This was investigated in a RCT where 106 participants were allocated to either 6 weeks of the guided self-help intervention (n = 52) or to a 6 weeks waitlist for the same intervention (n = 54). The primary outcome was depressive symptoms measured by Beck Depression Inventory-II (BDI-II). Secondary outcomes included anxiety symptoms measured by the Beck Anxiety Inventory (BAI) and the Hospital Anxiety and Depression Scale (HADS), and quality of life assessed with The Satisfaction With Life Scale (SWLS) and the EuroQol 5-dimension Self-Report Questionnaire (EQ-5D). Outcomes were assessed at baseline, post-intervention and 6-month follow-up. Primary analyses were performed on the intention-to-treat sample employing linear mixed models.

Results indicated that the intervention had significant effects relative to the waitlist control condition in reducing symptoms of depression (BDI-II and HADS) and anxious worry (HADS) from baseline to post-intervention, and in increasing global life satisfaction (SWLS). Between-group effect sizes were moderate to large (d = 0,65 – 1,10). There were no significant differences between groups on anxiety measured with BAI or health-related quality of life (EQ-5D). Treatment gains on depression and anxiety measures were largely maintained at 6-month follow-up, whereas increases in life satisfaction were partly maintained. A significantly larger proportion of participants in the intervention group (33 %) compared to the control group (9 %) recovered during treatment. Moderate levels of adherence (60 % completed treatment) and predominately positive ratings of treatment satisfaction, point to the overall acceptability of the intervention.

In conclusion, the intervention may be effective for primary care patients with mild to moderate depressive symptoms and can be suitable for implementation in primary health care as part of a stepped care approach. Further studies are needed to establish if the intervention is effective and acceptable when delivered by primary care therapists in regular practice.

Paper III

Høifødt, R.S., Mittner, M., Lillevoll, K.R., Katla, S.K., Kolstrup, N., Eisemann, M., Friborg, O., Waterloo, K. (2015). Predictors of response to Web-based cognitive behavioral therapy with face-to-face therapist support for depression: A Bayesian analysis. *Journal of Medical Internet Research* (submitted). doi:10.2196/jmir.4351

Most trials on internet-based treatments find a considerable level of non-response, and to date we know little about for whom this treatment is most effective. This paper explored predictors of response to the intervention combining MoodGYM and brief face-to-face therapist support.

Data from the RCT (Paper II) was used. In the RCT 106 participants were allocated to a treatment condition or to a delayed treatment condition. In this paper data from the treatment phase of both groups was merged to increase sample size (n = 82). Outcome was improvement in depressive symptoms during treatment (Beck Depression Inventory-II). Predictors were predominately chosen on the basis of previous research, but some were exploratory. Predictors included demographic variables, severity variables (e.g., pre-treatment depression and anxiety severity), cognitive variables (e.g., dysfunctional thinking), module completion, and treatment expectancy and motivation. Bayesian analysis was chosen because it enables the use of very flexible methods and can quantify the support for the null-hypothesis. Predictors of response were explored with a latent-class approach and by analysing whether predictors affected the slope of response.

We identified a two-class model distinguishing well between responders (74 %) and non-responders (26 %). Overall, the results suggested that treatment effects were comparable for men and women, for participants of various ages, across different levels of baseline depressive severity, and irrespective of the presence and severity of comorbid anxiety. Having a partner was the most robust predictor of a favourable response. A positive effect was also indicated for participants reporting higher life satisfaction at baseline and having had more depressive episodes. Higher scores on a measure of dysfunctional thinking predicted poorer treatment response. Within the group of responders, higher levels of dysfunctional thinking and baseline anxiety was associated with better treatment effects.

In conclusion, in a sample of mildly to moderately depressed patients effects of the present treatment do not seem to be related to gender, age, or the severity of depression or anxiety. The effect for more severe depression is uncertain. Marital status, life satisfaction, number of depressive episodes and level of dysfunctional thinking may predict treatment response. However, more studies are needed to confirm these findings.

Paper IV

Wilhelmsen, M., **Høifødt, R.S.**, Kolstrup, N., Waterloo, K., Eisemann, M., Chenhall, R., & Risør, M.B. (2014). Norwegian general practitioners' perspectives on implementation of a guided Web-based cognitive behavioral therapy for depression: A qualitative study. *Journal of Medical Internet Research, 16*(9), e208. doi: 10.2196/jmir.3556

Paper IV was a qualitative exploration of aspects perceived by GPs to influence implementation of guided Web-based CBT in their routine practice. The paper contributes to a better understanding of challenges in changing treatment practices in general practice.

In-depth interviews were conducted with a purposive sample of 11 GPs who had voluntarily attended a 3-day educational course introducing CBT and MoodGYM. The course advised GPs to recommend MoodGYM to their patients and provide brief follow-up consultations between modules focusing on process issues. A manual for follow-up was presented at the course and could be accessed online.

A thematic analysis using an inductive approach led to the identification of themes following a storyline from what attracted the GPs to learn CBT in the first place to how they applied guided Web-based treatment in their practice.

The GPs reported dissatisfaction with their standard treatment which was described as self-taught, informal and unstructured. This dissatisfaction, the common occurrence of depressed patients in their practice and limited access to specialist mental health care prompted a need to improve treatment and motivated them to learn CBT. Following the course most GPs took steps towards improving their treatment by recommending MoodGYM to their patients. Having MoodGYM as a concrete tool to use when treating depressed patients increased their feelings of competence and confidence in providing effective depression treatment and led to increased work satisfaction. GPs valued that MoodGYM added a structured agenda by providing a platform for delivering evidence-based psychoeducation and intervention, and by empowering patients to take active part in the recovery process. However, implementation was challenging, and module follow-ups were not successfully implemented due to time constraints, competing tasks, inadequate module knowledge and practical training, and difficulties with integrating the delivery of structured therapeutic content with a supportive patient-centered approach, the latter which is more in line with the role of the GP.

Discussion

Main Findings

The results from the first phase of the project suggest that internet-based CBT with therapist support may be an effective and acceptable treatment for primary care patients with mild to moderate symptoms of depression (Paper II). The intervention had significant positive effects on symptoms of depression and anxiety, and participants also experienced improved life satisfaction. In addition, more patients recovered in the intervention group compared to the control group. Treatment gains in terms of reduced symptoms of depression and anxiety were largely maintained at 6-month follow-up, and gains were partly maintained for life satisfaction.

Treatment response was comparable for men and women, for patients of various ages, and across varying levels of initial depressive severity (Paper III). In addition, patients with and without comorbid anxiety experienced comparable treatment effects. Patients living with a partner and those reporting higher life satisfaction showed a more favorable response to treatment. A more positive response was also indicated for individuals with more previous depressive episodes. Having a higher level of dysfunctional thinking at baseline may be a predictor of poorer treatment response.

Moderate non-adherence (40 %) and predominately positive ratings of treatment satisfaction among completers indicated that the intervention may be acceptable to patients (Paper II). By letting the CBT elements of the treatment be largely delivered by the program and giving the therapists a more supportive role, less strain is put on therapist resources. The present intervention is, therefore, of relatively low intensity and could have potential for use in a stepped care approach.

A review of previous literature conducted by the author (Paper I) indicated that computerised or internet-based CBT may be effective for mild to moderate depressive symptoms and may outperform treatment as usual when delivered in primary health care by primary care therapists without extensive training in delivering structured psychological interventions. This may include GPs or other professional groups such as practice nurses or social workers.

The second phase of the project aimed at implementing guided internet-based CBT in general practice. As GPs are central providers of primary health care in Norway, general practice was considered a valuable venue for implementation. Results from a qualitative study (Paper IV) of GPs who had attended an educational course introducing CBT in general and

guided self-help with MoodGYM in particular indicated that most GPs recommended MoodGYM to their patients. They perceived MoodGYM as a valuable tool for delivering evidence-based information and self-help to patients, and for empowering patients to become more active in the treatment process. Being able to offer something more than standard treatment also increased work satisfaction. However, follow-up consultations were generally not provided. Factors hindering implementation were time constraints, inadequate knowledge of MoodGYM, lack of practical training in delivering follow-ups, and difficulties with integrating structured discussions about program content in a supportive patient-centred dialogue.

The Effectiveness of Internet-based CBT with Face-to-Face Therapist Support

The results of the RCT were consistent with previous research on other guided internet-based interventions with regard to between-group effect sizes for depression, anxiety (HADS), and life satisfaction, rates of clinically significant improvement and recovery, and adherence (Andersson et al., 2005; Choi et al., 2012; Cowpertwait & Clarke, 2013; Johansson, Sjöberg, et al., 2012; Perini et al., 2009; Ruwaard et al., 2009; Vernmark et al., 2010). Effect sizes for guided internet-based interventions have generally been in the moderate to large range (Johansson & Andersson, 2012; D. Richards & Richardson, 2012; Titov, 2011). The effect size on BDI-II, the primary outcome measure, in the present study was well within this range, although, somewhat lower than average. These results place this study within the literature supporting the effect of guided internet-based interventions for depression.

Despite the positive effects seen in the trial, there is still room for improvement. At 7 weeks of treatment 33 % of the intervention group could be considered recovered based on their rate of improvement and end-point symptom scores (Seggar et al., 2002). At this point 15 % had completed treatment and 71 % had completed at least the first two modules, which include some of the most beneficial elements of the program (Christensen, Griffiths, Mackinnon, & Brittliffe, 2006). Applied to a stepped care model this means that about 35 % of the patients can leave treatment after receiving guided internet-based therapy. These are encouraging results, but still calls for action to improve outcomes. A reasonable goal would be to approach the target of a 50 % recovery rate set for the IAPT initiative in the UK (D. M. Clark et al., 2009). This target drew on the literature of RCTs of CBT.

Although, effects were largely maintained at 6-month follow-up, there was a tendency towards an increase in depressive symptoms as measured with HADS and a decrease in life satisfaction (SWLS) after the acute treatment phase. Including booster sessions may be a

means to improve maintenance of symptoms gains and prevent relapse. This is consistent with research on CBT delivered face-to-face which have found a stronger preventive effect on relapse and recurrence when continuation phase treatment is offered (Vittengl et al., 2007).

An adherence rate of 60 % is close to the average of 65 % for internet-based interventions but lower than the average completion rate of 85 % in face-to-face CBT, as reported in a recent meta-analysis (Van Ballegooijen et al., 2014). This meta-analysis points to different patterns of adherence in internet-based and face-to-face treatments with non-completers in internet-based treatments completing more of the intervention before discontinuing. Participants leaving treatment halfway or later may have experienced substantial improvement and leave because treatment is no longer needed. Nevertheless, efforts are still needed to improve adherence to internet-based interventions. Improved adherence may also positively contribute to outcomes as studies generally suggest a dose-response relationship between module completion and effectiveness (Donkin et al., 2011). A recent study indicated that this relationship may be more complex than a simple linear association, but supports the notion that greater engagement with the program increases the likelihood for beneficial effects (Donkin et al., 2013). In addition, qualitative research indicates that the experience of improvement serves as a motivational factor towards persistence in online treatment (Donkin & Glozier, 2012; Gerhards et al., 2011).

Program Design

Models aiming to inform the development of internet- or technology based behavioural interventions propose that features of the website affect website use which further influences mechanisms of change, behaviour change and symptom improvement (Mohr, Schueller, Montague, Burns, & Rashidi, 2014; Ritterband, Thorndike, Cox, Kovatchev, & Gonder-Frederick, 2009). A clear, accurate and understandable presentation of evidence-based content is of course a central prerequisite for intervention effects, but other features such as appearance of the website, how content is delivered and features aimed at enhancing participation are also important. Thus, designing effective programs includes an optimal balance between effective treatment elements promoting cognitive or behavioural changes and human-computer interaction design increasing engagement with program content (Hurling, Fairley, & Dias, 2006).

As many participants in online interventions may experience barriers such as time constraints, competing demands and incapacitating symptoms of anxiety and depression, it is important that programs include motivators, such as highlighting achievements and ongoing

reinforcement of participation, in order to overcome these barriers (Donkin & Glozier, 2012). A review focusing on persuasive system design called for a more systematic and theory-based approach to adaptation of Web-based interventions to increase adherence (Kelders et al., 2012). Especially, elements of dialogue support, such as offering praise and rewards for efforts or improvements made during treatment, were seldom used, even though their use was associated with improved adherence. Other findings suggest that including interactivity, tailoring and video-based material can increase usage and efficacy (Danaher, Boles, Akers, Gordon, & Severson, 2006; Hilvert-Bruce et al., 2012; Hurling et al., 2006; Johansson, Sjöberg, et al., 2012). These results are supported by qualitative research showing that a lack of personalisation, interaction and feedback from the program can reduce engagement, and that being able to control which activities and areas to focus on increases motivation (Donkin & Glozier, 2012). Other ways to reinforce participation and increase engagement could include giving initial hope through providing information about the effectiveness of the intervention and testimonials from other users, help participants make a schedule for their progress, give feedback on activities and progress, and include reminder systems (Donkin & Glozier, 2012; Gerhards et al., 2011; Hilvert-Bruce et al., 2012). Concepts such as the SilverCloud platform with its focus on interactivity, user choice, strategies to improve user engagement and a user-centered design process, incorporate many of these positive features (Sharry et al., 2013).

The MoodGYM program includes many positive elements. The program includes graphic content to illustrate key messages, symptoms are monitored throughout the program and tailored feedback is provided on several questionnaires. Participants are given many opportunities to practice and rehearse skills through various exercises, many of which use open text boxes where participants can fill in their own answers. This may increase the ability of users to relate program content to their personal situation. However, there is limited feedback on activities or progress in terms of symptom changes, and generally no personalisation or tailoring of content to the specific needs of the user. Modules were described as too long by several participants in the present study, and many reported skipping content that was judged unsuitable in order to manage time constraints (Wilhelmsen et al., 2013). More personalisation and tailoring of content may contribute to increased identification with the material and thereby increased motivation. It may also ensure that the program is more in line with the capacity of the patients. In addition, more initial information about the effectiveness of the program and testimonials from other users could, perhaps, have

given hope to participants. Hope of recovery was highlighted as a motivating factor by patients in the present study (Wilhelmsen et al., 2013).

Another issue is that the program was first launched in 2001, and considering the rapid development of computer technology, the user interface of the program is already becoming out of date. In a field developing as fast as computer and Internet technology, updating and re-evaluating interventions is likely necessary to be able to deliver a product meeting user expectations with regard to layout, appearance and functionality.

Perhaps most importantly, the program was originally developed for youth and young adults, and the style and examples are targeted towards this age group. This was commented on by participants in the study both in therapy sessions and in qualitative interviews and some expressed that they found the program superficial and the descriptions of problems and strategies too simplified (Wilhelmsen et al., 2013). Therapists emphasised the applicability of the principles to all age groups when introducing the program, but although, many managed to look beyond the specific examples and make use of the program, others expressed difficulties relating to the content. Between 50 % and 60 % of the adult sample of the current study allocated an unambiguous positive rating to the benefit and relevance of the program, and this indicates moderate satisfaction (Paper II). This suggests that the MoodGYM program has some limitations for use in adult populations, and points to the need for a variety of Web-based programs to match the preferences of a wider audience.

Therapist Support

Support is highlighted as a central factor influencing website use in the behaviour change model for internet interventions (Ritterband et al., 2009). The importance of support has been confirmed by research indicating both better adherence and improved outcomes for interventions including support compared to unguided interventions (Baumeister et al., 2014; Cowpertwait & Clarke, 2013; Kelders et al., 2012; D. Richards & Richardson, 2012; Spek et al., 2007). Although, the present study evaluated the intervention as a whole and, therefore, cannot distinguish between the different intervention elements, the impact of the therapist support was evident in the qualitative interviews (Lillevoll et al., 2013; Wilhelmsen et al., 2013). Participants described the face-to-face sessions as motivating and helpful, and some even expressed that they were a necessary condition for staying in treatment (Wilhelmsen et al., 2013). The possibility to freely share and discuss their problems with a professional, as well as receiving feedback, and to be supported and acknowledged were important aspects (Lillevoll et al., 2013). However, the sessions also complemented the MoodGYM program.

When participants struggled to understand or identify with material in the program, the sessions could be helpful with overcoming these problems (Lillevoll et al., 2013; Wilhelmsen et al., 2013). Through discussion with the therapist the content was made more elastic and patients were facilitated in the process of restructuring the content to fit their needs.

A lack of support in gaining a deeper understanding of program content and to maintain motivation to adhere to treatment has been shown to constitute a barrier to treatment success in previous trials (Bendelin et al., 2011; Gerhards et al., 2011). Studies also show that the lack of a therapeutic relationship and a feeling that no one is relying on their attendance can reduce accountability and motivation (Bickmore, Gruber, & Picard, 2005; Donkin & Glozier, 2012). The present intervention included both a therapeutic relationship and appointments where patients were expected to show up and to have completed a part of the self-help program. This may have increased accountability and motivation to persist, as was suggested by the qualitative interviews where some patients reported that the sessions with the therapist provided a deadline for completing the modules, and that this helped them find time to work with the program (Wilhelmsen et al., 2013).

Previous studies have also suggested that when interventions are free of cost, engagement and accountability can be reduced, and this may negatively affect both adherence and treatment effects (Donkin & Glozier, 2012; Hilvert-Bruce et al., 2012; Waber, Shiv, Carmon, & Ariely, 2008). Both access to the MoodGYM program and therapy sessions were free of cost in the present study, and it is possible that this may have reduced accountability and made it easier to skip appointments or drop out entirely for some participants. However, although paying a fee for treatment is the norm in Norway, introducing cost could have prevented both initial recruitment and continued engagement for some patients, and it may not be ethical in the context of investigating the effect of a new treatment model. A separate issue is whether the status of the therapist, being a psychologist versus a primary care therapist, may affect accountability. This is a question for further investigation.

What, how much and by whom?

Within the field of internet-based interventions it is still unclear what constitutes the optimal amount of support, what this support should consist of and what level of expertise that is necessary to provide support effectively (Andersson & Titov, 2014). Interventions providing support both before and during treatment yield on average better effects than interventions with either no support or support only before or during treatment (Johansson & Andersson, 2012). In addition, a significant correlation between effect size and therapist time has been

reported (Palmqvist, Carlbring, & Andersson, 2007). However, this seems to be true only up to a certain amount of therapist time and increasing the amount of support beyond this threshold does not facilitate further gains (Titov, 2011; Vernmark et al., 2010). For instance, a review concluded that high-intensity guided interventions yielded no better effects than low-intensity guided interventions (Titov, 2011).

In addition, studies show that interventions may be delivered effectively by providers with more limited expertise, e.g., technicians, service volunteers, nurse therapists and mental health workers with limited experience (Cavanagh et al., 2011; Farrand, Confue, Byng, & Shaw, 2009; Marks et al., 2003; Proudfoot et al., 2004; Titov et al., 2010). Comparable effects of administrative and clinical support are suggested both by meta-analytic results and by studies comparing the effect of interventions delivered by technicians versus by therapists (Baumeister et al., 2014; D. Richards & Richardson, 2012; E. Robinson et al., 2010; Titov et al., 2010). Effects appear to be similar across providers under conditions where the effective treatment elements are delivered by highly structured programs and providers receive supervision, but little is known about the optimal level of therapist expertise for less structured interventions (Andersson & Titov, 2014).

Administrative support can include guidance and feedback, but no active engagement in the patient's process such as goal setting, problem solving or discussions about treatment strategies (D. Richards & Richardson, 2012). These elements of therapeutic engagement may be included in clinical support. This highlights another issue, namely to what degree content of support impacts on the effectiveness of an intervention. In the review by Richards and Richardson (2012), the pooled effect size for studies including administrative support was lower (d = 0.58), but not significantly lower than for studies including clinical support (d = 0.78). In another review focusing on written self-help, a distinction was made between minimal-contact support and guided self-help, where the former provided a rationale for treatment and regular check-ins on progress (similar to administrative support), whereas the latter also included discussion of process issues (more in line with clinical support; Farrand & Woodford, 2013). This review concluded that support focusing on process issues (guided self-help) was less efficient for depression than minimal contact support. In this review treatment content and intensity were intertwined with minimal contact therapies corresponding to low-intensity guidance as defined in Titov et al. (< 3 hours; 2011), and most guided interventions providing high-intensity guidance (> 3 hours). Although, not fully generalisable to internet-based treatments, the results of this review, nevertheless, support the notion that more

intensive guidance including more clinical engagement does not seem to appreciably improve outcomes.

Efforts to determine the active elements of therapist support in internet-based interventions have been limited. One investigation coding therapist behaviours in a trial of internet-based treatment for generalised anxiety disorder suggested that outcome was positively associated with task reinforcement; that is, praise and reinforcement of tasks already completed by participants (Paxling et al., 2012). Allowing flexibility concerning deadlines for homework or module completion was, however, negatively associated with outcome. This may have been an inevitable response to non-adherent participants. However, the possible importance of having a clear deadline was supported by a study that found large positive effects for self-guided bibliotherapy for panic disorder when participants were given a clear deadline for completing the treatment (Nordin, Carlbring, Cuijpers, & Andersson, 2010). In line with this, some emphasise that therapist adherence in focusing on key issues and the minimising of therapist drift are aspects which may contribute to better outcomes (Andersson & Titov, 2014). In the present study participants were instructed to complete one module each week, but flexibility was allowed and patients could reschedule appointments and spend more time on a module if required. Being met with understanding and flexibility were factors that strengthened the sense of connectedness for patients in our study (Wilhelmsen et al., 2013), and according to Self-determination theory, connectedness is related to increased intrinsic motivation (Ryan & Deci, 2000). However, it is possible that for others an attitude signalising flexibility may have contributed to reduce accountability. In addition, the guideline script for the consultations allowed for variability, and treatment fidelity during sessions was not assessed. This is both a methodological limitation and an aspect of the intervention that may have influenced treatment outcomes negatively.

The present intervention can be considered a high-intensity guided intervention. Estimated mean total time spent by therapists was approximately 4 hours (M = 242 minutes, SD = 97), but the total time ranged from 1 to 8 hours (70 to 506 minutes; Paper II). This makes the current intervention more time-intensive than most other guided internet-based interventions. The role of the therapist was mainly supportive and facilitative, but process issues were discussed. Considering the results regarding the lack of difference between high- and low-intensity interventions and between clinical and administrative support, it would be interesting to investigate whether the results of our trial could be replicated using less intensive support. As two psychologists were therapists in this trial, further research is also necessary to determine if the treatment would be equally effective and acceptable when

delivered by GPs or other primary care therapists. This must be established before the treatment model can be recommended for use in a stepped care approach in regular primary health care.

Limitations and Strengths of the RCT

The present trial had several methodological limitations threatening the internal validity (see Paper II for a more detailed account). Perhaps the most prominent was the lack of allocation concealment which has been shown to be associated with inflated treatment effects (K. F. Schulz, Chalmers, Hayes, & Altman, 1995). The role of the researchers as therapists in the trial also introduced a risk of bias. Ideally, therapists should be kept blind to the treatment assignment of the patients to reduce bias. However, this was not possible if the patients were to meet the same therapist for both screening and treatment. This continuity was considered important from a clinical point of view given that the forming of the therapeutic alliance and getting to know the patient's background and condition started already during the screening interview. Patients could not be blinded to their group assignment, but were blind to the status of the waitlist as a control condition. This may have reduced any negative effects of randomisation. Another weakness of the design was that the comparison group did not receive any treatment, and, thus, one cannot partial out how much of the treatment effect is the effect of expectations or attention from the therapist, and how much is the effect of the specific intervention. A more potent comparator would have been treatment as usual, another treatment shown to have effect or an attention control condition. Finally, a limitation to be explored in further studies is the lack of differences between groups in functional improvement. This has implications for cost-utility and implementation (So et al., 2013). Therefore, further research is necessary before firm conclusions about effect and cost-effect can be drawn.

The study also had strengths. The sample was a heterogeneous group of mildly to moderately depressed primary care patients, and a substantial proportion had comorbid anxiety (33 %). Inclusion criteria were broad, and this increases the generalisability of the results to the wider population of depressed primary care patients. In addition, estimated uptake was satisfactory in that about 40 % of those invited to participate contacted the research group and met up for screening. Considering the extra hassles associated with participating in research, this number is encouraging, and even though the sample was self-selected, this further supports that our sample may be representative of a substantial proportion of mildly to moderately depressed primary care patients. Another strength was that

post-intervention measures were collected by a research assistant, unaware of group assignment. Unfortunately, no tests were performed to uncover whether the assistant was truly blinded. However, this has less impact on the present results, as all outcome measures were self-reports, although this is a limitation by itself.

For Whom is MoodGYM with Therapist Support Most Beneficial?

Based on data from the RCT, Paper III investigated prognostic predictors of response to the intervention. As the overall effect of a treatment is the average across participants and may not apply to individuals or subgroups within the sample, the identification of subgroups of participants with differential treatment response is an important line of inquiry (Kraemer, Frank, & Kupfer, 2006). The considerable level of non-response to internet-based treatments both in the present and previous trials makes this question even more relevant (e.g., Johansson, Sjöberg, et al., 2012; Perini et al., 2009; Ruwaard et al., 2009).

Analyses were performed on the collapsed data from the treatment-phase of the two groups. Despite this attempt to increase sample size, it still was limited. In addition, the lack of a comparison group precluded the identification of moderators of differential treatment response between treatments (Simon & Perlis, 2010). Therefore, no clear distinction could be made between moderators, non-specific predictors of response to treatments in general and non-specific predictors of good prognosis irrespective of treatment or not. The results must therefore be interpreted mainly as hypotheses to be tested in further studies. In addition, several variables that may have important contributions, such as personality variables and measures of the therapeutic alliance, were not included. Therefore, the present results give only a partial description of factors influencing treatment response (see Paper III for a more thorough account of study limitations).

The study, nevertheless, revealed some interesting findings that if confirmed in further studies may have practical implications. Using Bayesian methods enabled us to quantify the support for the null-hypothesis. This provides information about variables that are not associated with differential treatment response. Results showed substantial evidence that treatment response was unaffected by gender and age. This indicates that practitioners may recommend the present treatment model to men and women alike, and to patients of various age groups. The participants in our study were between 18 and 63 years of age, indicating the potential effectiveness across a wide age range.

We also found substantial evidence that the treatment had comparable effects for patients with various levels of depressive severity. Thus, within a group of mildly to

moderately depressed patients, the treatment may be beneficial irrespective of severity. However, as the sample did not include severely depressed individuals, no conclusions can be drawn for this group of patients. In addition, the treatment effects in terms of reduction of depressive symptoms were comparable for patients with or without comorbid anxiety irrespective of the severity of anxiety symptoms. In fact, among participants responding to treatment (showing some level of improvement), comorbid anxiety was associated with increased improvement of depressive symptoms. The treatment also yielded significant positive treatment effects for anxious worry, but not for physiological anxiety symptoms, as reported in Paper II. Put together this suggests that patients with comorbid anxiety may experience improvement in depressive symptoms at comparable rates as patients without comorbid anxiety, and may also experience significant reductions in anxious worry. The program may therefore be considered useful for patients with comorbid depression and anxiety. However, the intervention does not deal effectively with physiological symptoms of anxiety, and the degree to which patients recover from their anxiety by using the program is unknown. Practitioners should therefore be aware that anxiety symptoms, especially physiological symptoms, likely will need additional treatment. Others have approached the issue of comorbidity by developing transdiagnostic or tailored interventions, and such programs may be an effective way to deal with the substantial comorbidity between depression and anxiety (Johansson, Sjöberg, et al., 2012; Newby et al., 2013; Titov et al., 2011).

Although the above results indicate that the treatment model may be useful irrespective of gender, age and depressive and anxious severity, these results are not necessarily generalisable to all patients. The majority of the sample had a high school or higher education and all frequently used the Internet. Even though the MoodGYM program is easy to use, a basic level of computer literacy must be considered a necessary prerequisite. Some level of reading ability, cognitive ability and concentration are further prerequisites for making use of the program. MoodGYM was developed for adolescents and young adults, and the program has been used with participants as young as 12 years of age (Calear et al., 2009). This suggests that the content should be accessible for a wide audience. The wide applicability of CBT is supported by studies showing that CBT may be effective both for school-aged children and individuals with mild intellectual disabilities (Curry, 2001; Taylor, Lindsay, & Willner, 2008). However, the MoodGYM program is rich in text, and the patient's understanding and skills in CBT is mainly acquired through working alone with the program. Hence, some patients may need extra support in working through the program. The program

is probably of limited suitability for patients struggling severely with concentration, dyslexia or impaired cognitive abilities.

Some predictors of differential response were also identified. Marital status was the most robust predictor, and results indicated that married or cohabiting patients responded more favourably to treatment. This is in line with prior studies on CBT delivered face-to-face (Barber & Muenz, 1996; Fournier et al., 2009; Jarrett, Eaves, Grannemann, & Rush, 1991), whereas results have been mixed for internet-based CBT (Berger et al., 2011; Button et al., 2012; Farrer et al., 2014; Spek et al., 2008). Some studies have indicated that married patients benefit more from CBT, while single and non-cohabiting patients improve more with IPT (Barber & Muenz, 1996), implying that practitioners should consider IPT for the latter. However, for mildly to moderately depressed patients, IPT is unlikely to be available in Norwegian primary care. Qualitative interviews with participants from the current trial emphasised the motivational role of supportive relationships with partners, friends and family (Wilhelmsen et al., 2013). A general focus on maintaining relationships and avoiding isolation is an important aspect of treatment for all patients. In addition, encouraging patients to be open about their problems to important others and involve them in the treatment process may be a way to facilitate these supportive processes also for non-married and non-cohabiting patients.

A negative predictive effect was suggested for high levels of dysfunctional thinking as measured with the Warpy Thoughts Quiz, although, this effect was not supported by the Bayes factor analysis. A negative effect of dysfunctional attitudes has been found in several previous studies of face-to-face CBT (Blatt, Zuroff, Hawley, & Auerbach, 2009; Jarrett et al., 1991; Rude & Rehm, 1991; Sotsky et al., 1991). The results for internet-based CBT have been mixed (de Graaf et al., 2010; Donker, Batterham, et al., 2013; Warmerdam et al., 2013). In a prior study dysfunctional attitudes were found to be a moderator of treatment response as patients with severely dysfunctional attitudes responded better to IPT and those with lower levels experienced better effects with CBT (Sotsky et al., 1991). It has been suggested that individuals with lower dysfunctional attitudes may have a greater cognitive flexibility and may therefore, be better equipped to utilise cognitive techniques to improve their state, whereas focusing on such techniques may be overwhelming for patients with severe dysfunctional attitudes (Jarrett et al., 1991; Sotsky et al., 1991). Again, one may suggest recommending IPT to patients with higher levels of dysfunctional thinking, but this is not likely to be an available treatment option in most Norwegian primary care practices. What one may recommend is that practitioners get familiarised with the Warpy Thoughts Quiz and

evaluate the patient's scores on this quiz during the first follow-up. For patients with high scores special attention must be given to their subsequent progress and development during treatment. Depending on the overall appraisal of the severity of the condition, one may consider additional pharmacotherapy or referral to specialised treatment.

Higher life satisfaction was found to be a possible predictor of better response to treatment. A similar result was found in one earlier study of internet-based CBT (Andersson et al., 2004), but not in two more recent trials (Donker, Batterham, et al., 2013; Warmerdam et al., 2013). Research on the predictive effect of life quality or life satisfaction is scarce, but the present result serves as a hypothesis that life satisfaction may be a predictor of response, perhaps by tapping into aspects of illness severity not fully captured by symptom measures.

The finding that more depressive episodes apparently predicted a more positive treatment response is harder to interpret, and previous studies have yielded mixed results on this issue (Andersson et al., 2004; Button et al., 2012; J. D. Carter et al., 2011; Donker, Batterham, et al., 2013; Fournier et al., 2009; Jarrett et al., 1991; Ruwaard et al., 2009; Sotsky et al., 1991). Two different interpretations were considered in Paper III. One possibility is that participants with recurrent depression received more concurrent treatment with antidepressants than participants with single or no depressive episodes. However, most patients (~65 %) with recurrent depression did not receive additional treatment. If the use of combined pharmacotherapy and CBT affected the response of this group, this would be consistent with a meta-analysis showing some benefit of combination treatments in the short term (Cuijpers, van Straten, Warmerdam, et al., 2009). Another possibility is that the positive predictive effect of number of depressive episodes reflects the shorter duration of subsequent depressive episodes compared to first episodes in community samples, a finding which has been reported in epidemiological studies (Eaton et al., 1997; Spijker et al., 2002). Dependent on the interpretation the practical implications could vary from viewing recurrent depression as a predictor of good prognosis in terms of episode duration in community samples, to recommending that treatment with MoodGYM is combined with antidepressant medications for these patients. Evidently, additional research is needed to clarify this issue.

Is Web-based CBT Suitable for Implementation in General Practice?

Cognitive behavioural therapy in general and CBT-based self-help in particular has many advantageous features that may make such interventions suitable for use in general practice. The therapy is time-limited, structured and generally focuses on problems of the here-and-now (A. T. Beck et al., 1979; J. S. Beck, 1995). In addition, techniques are practical and well-

defined and patients are expected to take active part in their own recovery process (Blashki et al., 2008; Proudfoot, 2004).

General practitioners are usually the first health practitioners to meet patients struggling with mild to moderate mental disorders. Studies indicate that these patients are at an elevated risk for developing more serious mental problems, and GPs therefore have a unique opportunity to intervene at an early stage to prevent such development (Kessler et al., 2003). Another advantage in general practice is the continuity of care which is convenient for incorporating maintenance treatment or booster sessions after the initial intervention to prevent relapse of symptoms. However, GPs have a generalist role and this puts constraints on how much time can be devoted to learning new methods and to carrying out specific interventions in regular practice (Cape, Barker, Buszewicz, & Pistrang, 2000). Therefore, studies have recommended that more focus is given to patient activation and self-management (van Rijswijk, van Hout, van de Lisdonk, Zitman, & van Weel, 2009).

Self-help programs that can provide psychoeducation and teach core treatment techniques to patients can, therefore, be a viable treatment option for the general practice setting. This was supported by the results of Paper I which reviewed the literature on the effectiveness of CBT in primary health care and concluded that supported internet-based/computerised CBT may be effective in treating mild to moderate depression and anxiety also when delivered by primary care therapists. The robustness of these findings is limited by the relatively low number of included studies, and the variable methodological quality and sample size of the studies. Nevertheless, these results were further supported by a recent meta-analysis reporting that internet-based CBT delivered in primary care was more effective than no treatment and treatment as usual, yielding moderate and small effect sizes, respectively (Twomey, O'Reilly, & Byrne, 2015). Yet another recent meta-analysis found a small positive effect of guided self-help CBT compared to usual care for primary care patients (Linde et al., 2015). In this study guided self-help CBT included both computer- and internet-based CBT and written self-help material. Positive effects were also seen for CBT delivered using chat or telephone.

Both meta-analyses also reported positive effects of small to moderate size for CBT delivered face-to-face compared to usual care (Linde et al., 2015; Twomey et al., 2015). Positive small effects of CBT for depressed primary care patients have also been indicated in previous meta-analyses focusing mainly on face-to-face therapies (Cape, Whittington, Buszewicz, Wallace, & Underwood, 2010; Cuijpers, van Straten, van Schaik, & Andersson, 2009). As Paper I is a systematic review and we did not perform a meta-analysis, effects

cannot be compared. Nevertheless, the above findings differ somewhat from the results of Paper I where face-to-face CBT did not appear to enhance treatment effects relative to usual care in the majority of studies. A probable explanation for this difference is that our paper focused specifically on interventions delivered by primary care therapists without extensive specialised training in delivering structured psychological interventions. All four meta-analyses included treatments delivered by therapists with varying levels of expertise, and the majority of studies of face-to-face interventions used highly trained therapists. This may correspond with our finding that two studies that used therapists with both more initial training and more training and supervision as part of the study did indicate positive effects of face-to-face CBT when included as part of a complex intervention (Asarnow et al., 2005; Craske et al., 2005; Roy-Byrne et al., 2005). However, studies attempting to train primary care practitioners such as GPs and social workers to deliver CBT face-to-face all reported insignificant results compared to usual treatment (Kerfoot, Harrington, Harrington, Rogers, & Verduyn, 2004; King et al., 2002).

Several of the studies included in Paper I indicated that there may be a problem with the feasibility of training primary care therapists to deliver CBT face-to-face, possibly due to time constraints and/or a requirement for more extensive training (Kerfoot et al., 2004; King et al., 2002; van Boeijen et al., 2005). With CBT delivered online, the requirements for both training and time invested in consultations are likely to be reduced. This is also in line with the principles of stepped care which are increasingly being implemented in guidelines for depression care (National Institute for Health and Clinical Excellence, 2009; New Zealand Guidelines Group, 2008; Sinnema et al., 2013; The National Board of Health and Welfare (Socialstyrelsen), 2004).

As previously stated, studies indicate that CBT-based self-help may be delivered effectively by both expert practitioners and by practitioners with less formal training in delivering psychological therapy (Cavanagh et al., 2011; Farrand et al., 2009; Marks et al., 2003; Proudfoot et al., 2004; Titov et al., 2010). Few studies have investigated the effect of internet-based CBT when delivered by GPs. Two studies where patients used internet-based self-help between consultations with GPs trained in managing depression and anxiety, found positive effects of these interventions (Hickie et al., 2010; Shandley et al., 2008). However, the trial by Hickie et al. (2010) suffered from practical problems with resource constraints, poor recruitment of patients and high attrition, which resulted in a too small sample for drawing firm conclusions. Also, some more recently published studies have shown medium to large positive effects of internet-based CBT for depression (A. D. Williams & Andrews,

2013) and for mixed anxiety and depression (Newby et al., 2013; Newby et al., 2014) in primary care. In these studies primary care practitioners (40 % to 70 % GPs) provided patients with a prescription for internet-based CBT and supervised them through the course. These results point to the potential benefit of such treatment approaches in general practice, and highlight the need for further studies.

General Practitioners' Experiences with Implementing MoodGYM

As our team also encountered severe problems with poor patient recruitment, no study of the effectiveness of a treatment combining MoodGYM and GP-support, could be performed. However, using qualitative methods Paper IV explored the GPs' experiences with implementing MoodGYM following a 3-day training focusing on how to use CBT MoodGYM in practice.

The GPs in our study were motivated to improve their depression treatment by learning CBT, and almost all took important strides towards implementing MoodGYM in their daily practice by recommending the program to their patients. These are encouraging results as previous studies have indicated that GPs seldom recommend online self-help interventions to depressed patients, despite guideline recommendations (Hermens et al., 2014; Sinnema et al., 2013). The GPs in our study valued that MoodGYM made it possible for them to easily offer evidence-based psychoeducation and intervention to their patients. MoodGYM is based on CBT, a well-known and well-documented treatment model, which the GPs found credible. Research evidence regarding the effectiveness of MoodGYM had also been emphasised during the course. This enabled GPs to give information about the program and the theory upon which it is based, and to convey confidence in the program to their patients. This appears to be an important aspect as information from the two participants in the study who had not taken the course, as well as previous studies indicate that GPs are reluctant to recommend online resources to patients if they are not familiar with the content (Sinclair, Holloway, Riley, & Auret, 2013). As GPs have difficulties with finding time within their daily practice to seek out information about the credibility of existing online resources, educational efforts are required. The results of Paper IV indicate that a 3-day course may provide GPs with sufficient knowledge about internet-based CBT to promote recommendation.

How can the use of support be promoted?

Given the importance of support for improving adherence and outcomes of internet-based interventions (Cowpertwait & Clarke, 2013; Kelders et al., 2012; D. Richards & Richardson, 2012; Spek et al., 2007), recommendation of internet-based programs must be seen as only one step on the way towards successful implementation. In our study GPs generally did not provide follow-up consultations. Hindering factors were time constraints, competing tasks, inadequate knowledge of MoodGYM, and a lack of practical training. The interviews indicated that too little focus had been given to practical training in delivering the follow-ups during the course. In addition to this lack of formal training, the variety of patients seen in regular practice resulted in a lack of continuity and limited possibilities for getting familiarised with the program through ongoing training in their daily practice. As only 11 GPs were interviewed these results must be interpreted as only a partial description of the full range of GPs' experiences. Nevertheless, our results are highly consistent with several prior studies in general practice, where insufficient time, knowledge and skills have been emphasised as important barriers to providing optimal care or implementing new guidelines or interventions (Barley, Murray, Walters, & Tylee, 2011; Fleury et al., 2012; Hermens et al., 2014; Mykletun et al., 2010; Sinnema et al., 2013; van Rijswijk et al., 2009; Wiebe & Greiver, 2005).

These issues raise the question of how the use of support can be more successfully implemented. According to Normalisation Process Theory ensuring that the content, purpose and benefit of the intervention are clearly perceived by participants may enhance coherence; that is, how participants make sense of the intervention (Mair et al., 2012; Murray et al., 2010). The significance of these issues are also supported by a review suggesting that interventions are more easily adopted if sufficient information is given about how to use it, and when the benefits are clearly visible to adopters (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004). The GPs in our study felt they had too limited knowledge and training to provide the follow-ups, and this indicates that more time should be devoted during the course to give a more comprehensive overview of the MoodGYM program and how to provide follow-ups. The benefits of using MoodGYM were clearly demonstrated through a lecture from a patient who had used the program. However, the benefits of the follow-ups may have been less evident. This could possibly have been made clearer by emphasising the importance of support for outcome and adherence. Perceived benefit is crucial for implementation in general practice since this context is characterised by time pressure and competing tasks in consultations. If an intervention is not perceived as clearly beneficial it

will make little sense for GPs to prioritise this task over other competing tasks in a consultation, and engagement and effort to make the new practice work will suffer accordingly (Murray et al., 2010). Another aspect that may have caused decreased engagement is that the commencement of the trial was delayed and recruitment did not start until some months after the course. This may have caused some GPs to postpone trying out the new practice, and during this time the enthusiasm and engagement from the course may have faded.

Making practitioners "buy-in" to the idea of follow-ups would likely also increase engagement (cognitive participation) and the willingness to invest time and work in implementing the intervention (collective action; Murray et al., 2010). One way to successfully promote initial and sustained engagement and participation may be the use of champions; that is, early adopters of the intervention that can highlight the intervention as worthwhile and provide peer support to other participants (Greenhalgh et al., 2004; MacCarthy et al., 2013; Murray et al., 2010).

Compatibility

Another important aspect is the compatibility of the follow-ups with the GPs role and the existing work practices. Studies indicate that interventions are more easily implemented if they are more feasible, easy to use and compatible with the ways of working (innovation-system fit; Aarons, Hurlburt, & Horwitz, 2011; Greenhalgh et al., 2004; Meyers et al., 2012). In addition, the ability to refine and modify new practices to better suit ones needs also increases the chance of successful implementation. These are issues central to collective action (Murray et al., 2010). Discussions on how to overcome barriers and modify the follow-up sessions to fit into regular GP consultations may be one way to increase collective action, and this could have been a topic of the educational course. However, as barriers and mismatches with existing practices would probably become more apparent when attempting to use the intervention in daily practice, it is likely that this work may require subsequent meetings and supervision after completing the course. This is consistent with the results of a study of the implementation of a stepped care approach in primary care in the Netherlands (Franx et al., 2012). In this study structured meetings focusing on translating the intervention to suit local circumstances were found to be a facilitating factor for implementation.

The one GP who attempted to provide structured follow-ups in accordance with the guideline script, perceived the follow-ups as instrumental and in conflict with the GP role. It was difficult to integrate a structured discussion about progress and program content in a

supportive patient-centred dialogue focusing on problems experienced by the patient in daily life. As the latter was what both the GP and the patient wanted to focus on, follow-ups focusing on MoodGYM progress were experienced as unrewarding. This led to disengagement with the model and subsequently to abandoning the use of follow-up consultations. Previous research has shown that GPs see a patient-centred approach as an essential component of their role (Davidsen, 2008; Reeve et al., 2013), and that "tick box protocol-driven" instrumental approaches to care is seen as conflicting with this role (Davidsen & Reventlow, 2010; Reeve et al., 2013). Being able to take the patients agenda as a starting point and still link back to the MoodGYM modules to open up for a more structured discussion including CBT elements is likely to require a more in-depth knowledge of the program and more training in using CBT. Although, we cannot know whether more GPs would have experienced this role conflict had they attempted to provide follow-up consultations, the need for more knowledge and training was a recurring theme among GPs.

Learning strategies and training

Practical training in conducting the follow-ups may be another measure to increase collective action. In fact, previous research indicates that active learning strategies such as role-play, self-experiential work and reflective practice are most effective in enhancing the practical competencies and skills in CBT (Bennett-Levy, McManus, Westling, & Fennell, 2009). A prior study on face-to-face CBT in Norwegian general practice found structured supervision, group counselling and receiving feedback on video-recorded sessions to be promoting factors of use (Aschim et al., 2011). The importance of sufficient and ongoing training is also highlighted in literature focusing on implementation (Aarons et al., 2011; Greenhalgh et al., 2004; Mair et al., 2012; Meyers et al., 2012). Although, face-to-face CBT is likely to require more advanced skills than supporting internet-based CBT, an approach including more active learning strategies, as well as more longitudinal activities, such as supervision, could possibly have promoted the use of follow-ups in the present study.

The GPs' call for more knowledge about the MoodGYM program and more training in conducting follow-ups leaves us with a dilemma. The study by Aschim et al. (2011) suggests that use of CBT in general practice can be promoted by comprehensive longitudinal courses. This would, however, be much more inconvenient for the participating GPs who have hectic practices and whose salary is dependent upon treating patients. Indeed, constraints related to attending supervision were one of the limiting factors in the study by Aschim et al. (2011). The GPs of the current study were a selected group with an interest in improving their skills in

treating depression. However, by further increasing the length of the course and including longitudinal elements one would probably reach only an even smaller fraction of GPs. This conflicts with the aim of the present project, which was to disseminate knowledge about internet-based CBT more widely and not only to GPs prepared to invest substantial time and effort in learning the intervention. However, the exact amount of training and supervision needed for GPs to obtain the necessary competence and skills in delivering this sort of interventions, and the uptake of such training, cannot be answered by the present study.

Organisational factors

Even though comprehensive educational efforts may promote use of CBT among a selected group of GPs (Aschim et al., 2011), simple educational strategies generally seem to be ineffective as a means to improve depression management (Gilbody, Whitty, Grimshaw, & Thomas, 2003). In addition to individual level factors, implementation research and theories underline the important role of system and organisational characteristics such as financial incentives (Aarons et al., 2011; Greenhalgh et al., 2004; Grol & Wensing, 2004; Meyers et al., 2012; Proctor et al., 2009).

Time constraints were commonly mentioned as a limiting factor among GPs in our study. As one GP puts it, "It [guided internet-based CBT] isn't done in 20 minutes". The reimbursement schemes have generally encourage short consultations, and this has been identified as an impediment to giving optimal care for mental disorders, as well as hindering the use of CBT in previous studies (Aschim et al., 2011; Mykletun et al., 2010). Reimbursement structures supporting implementation has also been viewed as a success factor in previous international studies (Gidding et al., 2014). Addressing such organisational issues may encourage more use of CBT in consultations. Providing incentives to enable GPs to prioritise time to get familiar with the MoodGYM program could also be a step towards overcoming the barrier of inadequate knowledge of the modules. Last year the reimbursement schemes in Norway were changed to support the use of 25-minute consultations including structured therapy (Den Norske Legeforening, 2014). Had this change occurred prior to our trial, this could have affected implementation. However, another Norwegian study using a multifaceted intervention to implement new guidelines for sore throat and urinary tract infection illustrates the difficulties with implementing new strategies in general practice (Flottorp, Håvelsrud, & Oxman, 2003; Flottorp & Oxman, 2003). This study found little or no change of practice despite including tailored interventions to overcome identified barriers. One of these interventions was increasing the fees for telephone consultations to encourage

use of such consultations. This study concluded that active interventions such as outreach visits to participating practices may be effective; again emphasising the importance of ongoing support during the implementation process. It may also point to the importance of not only changing organisational structures such as reimbursement schemes, but also including supervision on how to use the remuneration structure most effectively to bill for their work (MacCarthy et al., 2013).

Multifaceted interventions including both clinician education, patient education and changes to the organisation of practice have been shown to be the most effective strategies for improving the management of depression in primary care (Gilbody et al., 2003; Rothman & Wagner, 2003). One effective organisational change is improvement of collaboration with specialist care (consultation-liasion; Gilbody et al., 2003). Enhanced collaboration with specialist mental health services has been underlined by GPs in several studies as an important factor for improving detection and treatment of depression (Fleury et al., 2012; Hermens et al., 2014; Mykletun et al., 2010; Sinnema et al., 2013). This may include possibilities for quick consultations about diagnosis and treatment, access to supervision and counselling, as well as better communication about patients' treatment after referral. This may be relevant also in the context of using guided internet-based CBT. However, in this case the ability to receive supervision from someone with knowledge of MoodGYM, in addition to the possibility of making more general inquiries about diagnosis and treatment would be preferable.

Another organisational change shown to be effective is the addition of follow-up, monitoring and support by nurses, practice counsellors or other professional groups in primary care (case mangement; Gilbody et al., 2003). Thus, another approach to implementation would be to train other professional groups in primary care to deliver the intervention. In this way depression care would be shared between these practitioners and GPs. This may be one way to overcome the barriers of time constraints and competing tasks faced by GPs. The IAPT initiative in the UK has trained a whole new work force of well-being practitioners to deliver low-intensity interventions for depression and anxiety as part of a stepped care approach (D. M. Clark, 2011). Results from the first phase of the program have been encouraging with regard to patient throughput, quality of treatment and patient outcomes (D. M. Clark, 2011; D. M. Clark et al., 2009). Positive results also come from research trials showing that internet-based CBT supported by e.g., practice nurses can be an effective treatment for depression in primary care (Marks et al., 2003; Proudfoot et al., 2004). This suggests that educating low-intensity therapists to be employed within GP practices or in a

primary care service specialised in delivering low-intensity interventions such as guided internet-based CBT, may be a way to make such treatments widely accessible to patients.

Stepped Care

The present intervention could be a useful part of a stepped care approach to depression treatment if delivered effectively by primary care therapists. However, the MoodGYM program can only be one piece of the puzzle, and provision of stepped care would require that a range of effective low- and high-intensity interventions were available in primary care or in collaboration with specialised services. In addition, an essential component of stepped care is systematic initial assessment of depression severity in order to initiate appropriate treatment, as well as monitoring of symptoms during treatment to make decisions about stepping-up in case of poor treatment response (Hermens et al., 2014; Sinnema et al., 2013). The present study did not address this point, but previous international studies show that implementing systematic monitoring of symptoms using validated instruments in general practice can be challenging (Gidding et al., 2014; Hermens et al., 2014; Sinnema et al., 2013). Consequently, our studies provide encouraging results with regard to the possible effectiveness of a guided internet-based treatment for depression. However, further studies are needed to evaluate the effect of the intervention when delivered in regular practice, and clearly, a more large-scale initiative will be necessary to make stepped care for depression part of the regular health services in Norway. One such project is the MasterMind project, which is a collaboration between 11 European countries, including the Troms-region in Northern Norway. This project aims to improve access to and quality of depression treatment by doing a large-scale implementation and evaluation of computerised CBT and collaborative care facilitated by video conference (MasterMind, 2015). The treatment model to be implemented in Norway builds on the experiences from the current project.

Conclusion and Future Directions

Overall, our studies indicate that a treatment model including the MoodGYM program and brief face-to-face therapist support may be effective and acceptable for primary care patients with mild to moderate depressive symptoms. The treatment can be suitable for patients with varying levels of initial depressive severity and for patients with or without comorbid anxiety. Treatment effects were also comparable for men and women and for patients of various ages.

The MoodGYM program and the support sessions complemented each other. The MoodGYM program provided knowledge about CBT principles and techniques, and when

participants struggled with identifying with program content the sessions with the therapist could be helpful in overcoming these problems. However, there is still room for improvement, both in terms of adherence and rates of recovery, and the effectiveness of the intervention when delivered in regular practice remains to be evaluated. In addition, moderate satisfaction with MoodGYM in the present adult sample points to the need for a variety of Web-based programs to meet the preferences of a wider audience. Computer and Internet technology has developed immensely during the last decade and more is known about how e.g., persuasive technology can be used to engage and support participants through internet-based treatments. Thus, increased adherence and effects can likely be achieved by improving program design, and future investigations should also aim to determine the optimal content and intensity of support. Another important line of research is to increase our knowledge about for whom such treatments are most suitable (or unsuitable) in order to inform treatment selection.

Previous trials indicate the effectiveness of internet-based CBT when delivered in primary care by primary care therapists. Our study shows that GPs may become confident in recommending the program to their patients after an educational course. However, follow-up sessions were generally not provided due to barriers such as time constraints, and a lack of knowledge and training. This shows that other approaches are needed to successfully implement this treatment in primary care. More comprehensive educational approaches may reach a selected group of GPs. However, multifaceted interventions including patient education, clinician education and organisational changes such as changing reimbursement structures will be needed to implement such treatments more widely. Experiences from other countries suggest that successful implementation of treatments such as guided internet-based interventions, may be achieved by training other professional groups to deliver these interventions in primary care or in collaboration with specialised services as part of a stepped care approach. Further studies are needed to investigate how such a model would work in Norwegian primary care. Furthermore, if the aim is to develop and implement a model for stepped depression care within Norwegian health services, large-scale initiatives will be necessary.

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Appendix I

Measures

HAD

Hospital Anxiety & Depression Scale (januar 1999)

Navn: _____ Fødselsdato: _____

Dato for utfylling: _____ Pasient nr.: _____

Behandler: _____

Rettledning

Legen er klar over at følelser spiller en stor rolle ved de fleste sykdommer. Hvis legen vet mer om følelser, vil han/hun bli bedre i stand til å hjelpe deg.

Her kommer noen spørsmål om hvorledes du føler deg. For hvert spørsmål setter du kryss for ett av de fire svarene som best beskriver dine følelser den siste uken. Ikke tenk for lenge på svaret – de spontane svarene er best.

1. Jeg føler meg nervøs og urolig

- ❑ 3 Mesteparten av tiden
- ❑ 2 Mye av tiden
- ❑ 1 Fra tid til annen
- ❑ 0 Ikke i det hele tatt

2. Jeg gleder meg fortsatt over tingene slik jeg pleide før

- ❑ 0 Avgjort like mye
- ❑ 1 Ikke fullt så mye
- ❑ 2 Bare lite grann
- ❑ 3 Ikke i det hele tatt

3. Jeg har en urofølelse som om noe forferdelig vil skje

- ❑ 3 Ja, og noe svært ille
- ❑ 2 Ja, ikke så veldig ille
- ❑ 1 Litt, bekymrer meg lite
- ❑ 0 Ikke i det hele tatt

4. Jeg kan le og se det morsomme i situasjoner

- ❑ 0 Like mye nå som før
- ❑ 1 Ikke like mye nå som før
- ❑ 2 Avgjort ikke som før
- ❑ 3 Ikke i det hele tatt

5. Jeg har hodet fullt av bekymringer

- ❑ 3 Veldig ofte
- ❑ 2 Ganske ofte
- ❑ 1 Av og til
- ❑ 0 En gang i blant

6. Jeg er i godt humør

- ❑ 3 Aldri
- ❑ 2 Noen ganger
- ❑ 1 Ganske ofte
- ❑ 0 For det meste

7. Jeg kan sitte i fred og ro og kjenne meg avslappet

- ❑ 0 Ja, helt klart
- ❑ 1 Vanligvis
- ❑ 2 Ikke så ofte
- ❑ 3 Ikke i det hele tatt

8. Jeg føler meg som om alt går langsommere

- ❑ 3 Nesten hele tiden
- ❑ 2 Svært ofte
- ❑ 1 Fra tid til annen
- ❑ 0 Ikke i det hele tatt

9. Jeg føler meg urolig som om jeg har sommerfugler i magen

- ❑ 0 Ikke i det hele tatt
- ❑ 1 Fra tid til annen
- ❑ 2 Ganske ofte
- ❑ 3 Svært ofte

10. Jeg bryr meg ikke lenger om hvordan jeg ser ut

- ❑ 3 Ja, jeg har sluttet å bry meg
- ❑ 2 Ikke som jeg burde
- ❑ 1 Kan hende ikke nok
- ❑ 0 Bryr meg som før

11. Jeg er rastløs som om jeg stadig må være aktiv

- ❑ 3 Uten tvil svært mye
- ❑ 2 Ganske mye
- ❑ 1 Ikke så veldig mye
- ❑ 0 Ikke i det hele tatt

12. Jeg ser med glede frem til hendelser og ting

- ❑ 0 Like mye som før
- ❑ 1 Heller mindre enn før
- ❑ 2 Avgjort mindre enn før
- ❑ 3 Nesten ikke i det hele tatt

13. Jeg kan plutselig få en følelse av panikk

- ❑ 3 Uten tvil svært ofte
- ❑ 2 Ganske ofte
- ❑ 1 Ikke så veldig ofte
- ❑ 0 Ikke i det hele tatt

14. Jeg kan glede meg over gode bøker, radio og TV

- ❑ 0 Ofte
- ❑ 1 Fra tid til annen
- ❑ 2 Ikke så ofte
- ❑ 3 Svært sjelden

Takk for utfyllingen!

Sum A:

1+3+5+7+9+11+13= _____

Sum D:

2+4+6+8+10+12+14= _____

Sum A + D: _____

Skåringsveiledning til HAD

(Hospital Anxiety and Depression Scale)

Selvutfylling på sju angst- og depresjonsspørsmål.

Sum A eller Sum D:
En skår på 11 eller mer regnes for å være et tilfelle av angst eller depresjon som vil trenge nærmere utredning (med SPIFA for eksempel) og eventuelt behandling. En skår på 8-10 anses som et mulig tilfelle, og lavere skår uttrykker en viss symptombelastning, som kan ha betydning samlet sett, men som i seg selv ikke krever spesifikk behandling av angst eller depresjon.

Sum A + Sum D:
Det er også mulig å legge sammen angst- og depresjonsskåren til en totalskår fordi en del pasienter har en blanding av angst og depresjon. Et tilfelle vil da ha en totalskår på 19 eller mer. Et mulig tilfelle vil ha en skår på 15-18. Skår på over 15 vil trenge oppfølging og eventuelt behandling.

Dersom inntil to spørsmål på HAD er ubesvart, vil det være mulig å beregne totalskår. Sumskåren deles med antallet besvarte spørsmål og svaret ganges med 14. Dette gir estimert totalskår.

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1. LYKKE

ID# / Dato:

Alt tatt i betraktning, hvor lykkelig er du?
(sett ett kryss).

Ekstremt ulykkelig	0	1	2	3	4	5	6	7	8	9	10	Ekstremt lykkelig
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

2. TRIVSEL OG LIVSFORHOLD

Nedenfor står det fem utsagn om tilfredshet med livet som et hele. Deretter står det to utsagn om syn på din egen helse. Vis hvor enig eller uenig du er i hver av påstandene ved å sette et kryss i rubrikken for det tallet du synes stemmer best for deg (sett ett kryss for hvert utsagn).

	Helt uenig 1	2	3	4	5	6	Helt enig 7
På de fleste måter er livet mitt nær idealet mitt	☐	☐	☐	☐	☐	☐	☐
Mine livsforhold er utmerkede	☐	☐	☐	☐	☐	☐	☐
Jeg er tilfreds med livet mitt	☐	☐	☐	☐	☐	☐	☐
Så langt har jeg fått de viktige tingene jeg ønsker i livet	☐	☐	☐	☐	☐	☐	☐
Hvis jeg kunne leve livet på nytt, ville jeg nesten ikke forandret på noe	☐	☐	☐	☐	☐	☐	☐
Jeg ser lyst på min framtidige helse	☐	☐	☐	☐	☐	☐	☐
Ved å leve sunt kan jeg forhindre alvorlige sykdommer . .	☐	☐	☐	☐	☐	☐	☐

3. BESKRIVELSE AV DIN HELSETILSTAND

ID# / Dato:

Vis hvilke utsagn som passer best på din helsetilstand i dag ved å sette ett kryss i en av rutene utenfor hver av de fem gruppene nedenfor:

1.1 Gange

- ☐ Jeg har ingen problemer med å gå omkring
- ☐ Jeg har litt problemer med å gå omkring
- ☐ Jeg er sengeliggende

1.2 Personlig stell

- ☐ Jeg har ingen problemer med personlig stell
- ☐ Jeg har litt problemer med å vaske meg eller kle meg
- ☐ Jeg er ute av stand til å vaske meg eller kle meg

1.3 Vanlige gjøremål (f.eks. arbeid, studier, husarbeid, familie- eller fritidsaktiviteter)

- ☐ Jeg har ingen problemer med å utføre mine vanlige gjøremål
- ☐ Jeg har litt problemer med å utføre mine vanlige gjøremål
- ☐ Jeg er ute av stand til å utføre mine vanlige gjøremål

1.4 Smerte og ubehag

- ☐ Jeg har verken smerte eller ubehag
- ☐ Jeg har moderat smerte eller ubehag
- ☐ Jeg har sterk smerte eller ubehag

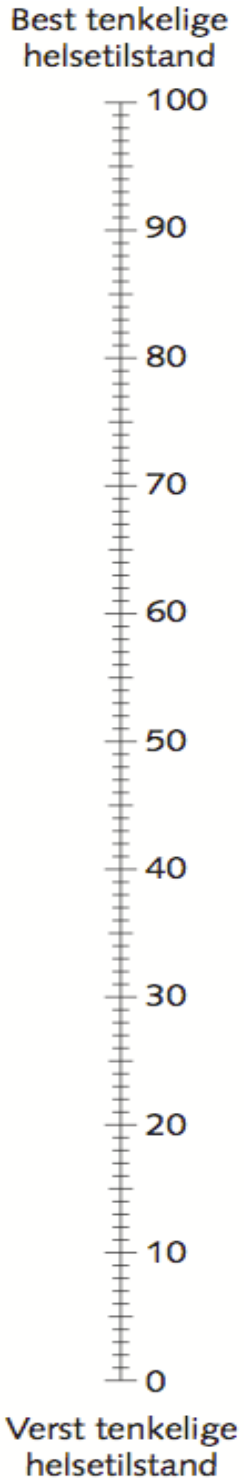
1.5 Angst og depresjon

- ☐ Jeg er verken engstelig eller deprimert
- ☐ Jeg er noe engstelig eller deprimert
- ☐ Jeg er svært engstelig eller deprimert

1.6 For at du skal kunne vise oss hvor god eller dårlig din helsetilstand er, har vi laget en skala (nesten som et termometer), hvor den beste helsetilstanden du kan tenke deg er markert med 100 og den dårligste med 0.

Vi ber om at du viser din helsetilstand ved å trekke ei linje fra boksen nedenfor til det punkt på skalaen som passer best med din helsetilstand.

Nåværende helsetilstand



Tilfredshet med behandlingen

1. Alt i alt, hvor fornøyd er du med behandlingstilbudet du fikk?

Svært misfornøyd Svært fornøyd

1 2 3 4 5

2. Er dine plager blitt bedre eller verre sammenlignet med før du startet behandlingen?

Mye bedre Verken eller Mye verre

1 2 3 4 5

3. Hvilket utbytte har du hatt av å bruke Internettprogrammet MoodGYM?

Ikke noe utbytte Svært stort utbytte

1 2 3 4 5

4. I hvilken grad fokuserte MoodGYM på problemstillinger som var relevante for deg?

I svært liten grad I svært høy grad

1 2 3 4 5

5. I hvilken grad opplevde du at oppgavene i MoodGYM var nyttige for deg?

I svært liten grad I svært høy grad

1 2 3 4 5

6. Hvilket utbytte har du hatt av oppfølgingstimene?

Ikke noe utbytte Svært stort utbytte

1 2 3 4 5

7. Hva synes du om antallet konsultasjoner du har fått?

Altfor få		Akkurat passe		Altfor mange
1	2	3	4	5

8. Hvordan opplevde du kontakten med din behandler?

Svært negativ				Svært positiv
1	2	3	4	5

9. Ville du anbefalt denne typen behandling til en venn som hadde et lignende problem?

Nei, definitivt ikke				Ja, definitivt
1	2	3	4	5

Alkobruk - en privatsak?

Testen nedenfor er enkel og gir ingen fasitsvar. Men den kan hjelpe deg å kartlegge ditt eget alkoholkonsum. La gjerne andre du kjenner fylle ut testen. Den er et godt utgangspunkt for diskusjon.

1. **Hvor ofte drikker du alkohol?**
   - Aldri……0
   - Månedlig eller sjeldnere…..1
   - To til fire ganger i mnd.....2
   - To til tre ganger i uka.....3
   - Minst fire ganger i uka……4

2. **Hvor ofte føler du at du ikke kan stoppe å drikke når du først er i gang?**
   - Aldri……0
   - Sjelden……1
   - Noen ganger i mnd…….2
   - Noen ganger i uka……..3
   - Nesten daglig……..4

3. **Hvor ofte drikker du mer enn seks alkoholenheter?**
   - Aldri……0
   - Månedlig eller sjeldnere….1
   - Noen ganger i mnd…….2
   - Noen ganger i uka……..3
   - Nesten daglig……..4

4. **Hvor ofte har du skyldfølelse pga. alkohol?**
   - Aldri……0
   - Sjelden……1
   - Noen ganger i mnd…….2
   - Noen ganger i uka……..3
   - Nesten daglig……..4

5. **Hvor mange drinker drikker du på en typisk "drikkedag"?**
   - 1-2……..0
   - 3-4……1
   - 5-6……..2
   - 7-9……..3
   - Minst 10……4

6. **Hvor ofte har du "blackout" og husker lite fra kvelden før?**
   - Aldri……0
   - Sjelden……1
   - Noen ganger i mnd…….2
   - Noen ganger i uka……..3
   - Nesten daglig……..4

7. **Hvor ofte starter du "dagen-derpå" med alkohol?**
   - Aldri……0
   - Sjelden……1
   - Noen ganger i mnd…….2
   - Noen ganger i uka……..3
   - Nesten daglig……..4

8. **Har du eller andre blitt skadet pga. ditt alkoholbruk?**
   - Aldri……0
   - Månedlig eller sjeldnere….1
   - Noen ganger i mnd…….2
   - Noen ganger i uka……..3
   - Nesten daglig……..4

9. **Hvor ofte fører alkoholbruken til at du bryter avtaler, unnlater å gjøre ting du har planlagt, holder deg hjemme fra jobben o.l.?**
   - Aldri……0
   - Månedlig eller sjeldnere….1
   - Noen ganger i mnd…….2
   - Noen ganger i uka……..3
   - Nesten daglig……..4

10. **Har slekt, venner, kolleger eller lege engstet seg over ditt alkoholforbruk og bedt deg drikke mindre?**
    - Nei……...0
    - Ja, men ikke det siste året....2
    - Ja, i løpet av det siste året…4

En drink= 1 alkoholenhet (AE)
1AE inneholder ca. 12,8 gr. Alkohol og tilsvarer:
1 glass hetvin (8cl)
1 vanlig glass rød/hvit vin (12cl)
1 drink (4cl)
½ flaske pils(35cl)

½ flaske lettøl = 0,5 AE
1/1 flaske rød/hvit vin = 6AE
1/1 flaske brennevin = 18AE

Slik tolker du svarene dine:
Under 11 poeng: Dette ser bra ut. Er du sikker på at du har svart riktig, kan du ta det med ro. Dine alkoholvaner er til å leve med, i alle fall hvis svaret ditt på spørsmål 3 er *sjelden* eller *aldri*
11-15 poeng: Du er i faresonen og kan risikere å skade deg selv eller andre. Tenk gjennom ditt forbruk - når og hvordan kan du redusere det?
Over 15 poeng: Du drikker for mye og bør redusere alkoholforbruket omgående. Vurder også om du bør søke hjelp

DUDIT

Drug Use Disorders Identification Test

Her er noen spørsmål om stoff. Vi er takknemlige om du svarer så grundig og ærlig som mulig ved å markere det alternativ som gjelder for deg.

☐ **Mann** ☐ **Kvinne** **Alder** ☐☐

1. Hvor ofte bruker du andre stoff enn alkohol? (Se listen over stoff på baksiden.)	Aldri ☐	1 gang i måneden eller sjeldnere ☐	2-4 ganger i måneden ☐	2-3 ganger i uken ☐	4 ganger i uken eller mer ☐
2. Bruker du flere enn ett stoff ved ett og samme tilfelle?	Aldri ☐	1 gang i måneden eller sjeldnere ☐	2-4 ganger i måneden ☐	2-3 ganger i uken ☐	4 ganger i uken eller mer ☐
3. Hvor mange ganger i løpet av en typisk dag tar du stoff, når du tar stoff?	0 ☐	1 - 2 ☐	3 – 4 ☐	5 – 6 ☐	7 eller flere ☐
4. Hvor ofte blir du kraftig påvirket av stoff?	Aldri ☐	Sjeldnere enn en gang i måneden ☐	Hver måned ☐	Hver uke ☐	Daglig eller nesten hver dag ☐
5. Har du det siste året opplevd at lengselen etter stoff har vært så sterk at du ikke kunne stå i mot?	Aldri ☐	Sjeldnere enn en gang i måneden ☐	Hver måned ☐	Hver uke ☐	Daglig eller nesten hver dag ☐
6. Har det hendt at du i løpet av det siste året ikke kunne slutte å ta stoff når du først hadde begynt?	Aldri ☐	Sjeldnere enn en gang i måneden ☐	Hver måned ☐	Hver uke ☐	Daglig eller nesten hver dag ☐
7. Hvor ofte i løpet av det siste året har du tatt stoff og så latt være å gjøre noe som du burde ha gjort?	Aldri ☐	Sjeldnere enn en gang i måneden ☐	Hver måned ☐	Hver uke ☐	Daglig eller nesten hver dag ☐
8. Hvor ofte i løpet av det siste året har du hatt behov for å starte dagen med å ta stoff etter stort stoffinntak dagen før?	Aldri ☐	Sjeldnere enn en gang i måneden ☐	Hver måned ☐	Hver uke ☐	Daglig eller nesten hver dag ☐
9. Hvor ofte i løpet av det siste året har du hatt skyldfølelse eller dårlig samvittighet fordi du har brukt stoff?	Aldri ☐	Sjeldnere enn en gang i måneden ☐	Hver måned ☐	Hver uke ☐	Daglig eller nesten hver dag ☐
10. Har du eller noen andre blitt skadet (psykisk eller fysisk) på grunn av din bruk av stoff?	Nei ☐	Ja, men ikke i løpet av det siste året ☐		Ja, i løpet av det siste året ☐	
11. Har en slektning eller venn, lege eller sykepleier, eller noen andre vært urolige for din bruk av stoff, eller sagt til deg at du bør slutte med stoff?	Nei ☐	Ja, men ikke i løpet av det siste året ☐		Ja, i løpet av det siste året ☐	

Snu arket for å se listen over stoff

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LISTE OVER STOFF

(OBS! IKKE ALKOHOL)

Cannabis	Amfetamin, sentralstim.	Kokain	Opiater	Hallucinogener	Løsningsmiddel	GHB och øvrige
Cannabis Cannabisolje Hasj Marihuana	Amfetamin Betelnøtt Concerta Dexamin Equasym Fenmetralin Khat Metamfetamin Metylfenidat Modafinil Modiodal Ritalin	Crack Freebase Kokablad Kokain Kokainbase Kokapasta	Heroin Opium Røyke-heroin	2C-B, DOB DMT (mimosa) Ecstasy (MDMA) Fleinsopp Ketalar/Ketamin LSD Magic mushrooms Meksikansk sopp Meskalin/Peyote Muskat PCP Piggeple Psilocybin	Bensin Gass Lim Løsemidler Trikloretylen Tynner	Amylnitritt (poppers) Anabole steroider Antikolinergika (Disipal, Akineton) GHB, GBL Lystgass

TABLETTER – LEGEMIDLER

Tabletter regnes som stoff når du tar:

- legemidler mer eller oftere enn legen har foreskrevet
- tabletter for å ha det moro, føle deg bra, bli "høy", eller prøve ut effekten av dem
- tabletter som du har fått av en slektning eller venn
- tar tabletter som du har kjøpt "svart" eller stjålet

Beroligende legemidler og/eller sovetabletter

Alopam	Karisoprodol	Stilnoct
Aprazolam	Klometiazol	Valium
Apodorm	Klonazepam	Vival
Ativan	Lorazepam	Xanor
Barbital	Midazolam	Xanor dep.
Diazepam	Mogadon	Zolpidem
Dormicum	Nitrazepam	Zopiclone
Fenemal	Oxazepam	Zopiklon
Fenobarbital	Rivotril	
Flunitrazepam	Rohypnol	
Flunipam	Sobril	
Heminevrin	Somadril	
Imovane	Stesolid	

Smertestillende legemidler

Actiq	Kapanol	OxyContin
Anervan	Ketalar	OxyNorm
Aporex	Ketamin	Pallodon
Apotekets sterke -Hostesirup	Ketobemidon	Paralgin
Buprenorfin	Ketogan	Paralgin- - Forte/Major/Minor
Cosylan	Ketorax	Petidin
Dekstropropok-syfen	Kodein	Pinex
Dolcontin	Leptanal	Pinex- - Forte/Major
Durogesic	Matrifen	Solvipect Comp
Etylmorfin	Meprobamat	Suboxone
Fentanyl	Metadon	Subutex
Fortralin	Morfin	Temgesic
Hydrokon	Morfin-scopolamin	Tramadol
Hydromorfon-klorid	Nobligan	Tramagetic
	Norspan	
	Oksykodon	

Tabletter regnes IKKE som stoff når de er foreskrevet av lege
og du tar dem slik legen sier at du skal (både mengde og hyppighet).

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Negative Tanker Testen /Warpy Thoughts Quiz

Spørsmål

Hver del blir besvart med følgende alternativer:

1- Svært enig
2- Enig
3- Verken enig eller uenig
4- Uenig
5- Svært uenig

Behovet for å bli akseptert av andre:

- Hvis folk kritiserer meg er jeg en verdiløs person
- Andre menneskers aksept av meg er svært viktig
- Jeg kan få alle til å like meg, hvis jeg bare prøver hardt nok
- Det viktigste i verden for meg er å bli akseptert
- Jeg synes det er helt umulig å gå imot andres ønsker
- Hvis ikke jeg får ros og skryt hele tiden, føler jeg med verdiløs

Behovet for å bli elsket:

- Livet er helt uutholdelig hvis jeg ikke er elsket av familien min
- Hvis jeg ikke er elsket er det fordi det ikke går an å elske meg
- Hvis jeg elsker noen som ikke elsker meg, så er det fordi jeg er utilstrekkelig
- Jeg må hele tiden få høre at jeg er elsket for å føle meg trygg
- Hvis jeg var en bedre person så ville jeg ha blitt elsket
- For å være lykkelig må jeg ha noen som virkelig elsker meg

Behovet for å lykkes:

- Jeg kan ikke føle meg likeverdig med andre med mindre jeg er bedre enn dem i noe
- Jeg føler meg bare verdsatt når jeg når mine mål
- Min fremgang i livet bestemmer mine mål
- Jeg må lykkes på alle områder som er viktige for meg
- Livet er meningsløst hvis jeg ikke har noen mål å strebe etter
- Uten suksess i livet er det umulig å bli lykkelig

Behovet for å være perfekt:

- Jeg ser ikke vitsen med å gjøre noe dersom det ikke blir gjort helt perfekt
- Det finnes ingen andreplasser i livet
- Ting må bli utført til en viss standard ellers er det ikke noe vits å gjøre dem
- Hvis jeg gjør feil vil andre tenke dårlig om meg
- Hvis jeg ikke gjør ting helt perfekt, så liker jeg ikke meg selv noe særlig
- Jeg klarer sjelden å nå mine egne høye standard

Følelsen av kunne påvirke / være ansvarlig for andres følelsesmessige reaksjoner

- Jeg kan forhindre at folk blir opprørt ved å tenke på hva de trenger
- Hvis jeg har kranglet med mine venner så må det ha vært min feil
- Jeg bør være i stand til å blidgjøre alle mennesker
- Jeg er ansvarlig for andres lykke
- Hvis folk er ukomfortable rundt meg, så må det være min feil
- Hvis folk rundt meg er opprørt, så er jeg alltid bekymret for at det er min feil

Lykke er avhengig av ting rundt meg

- Jeg kan bare være lykkelig hvis jeg har de gode tingene i livet
- Hvis ikke jeg har dyre ting, så vil folk ikke akseptere meg
- Dersom jeg ble belønnet for de målene jeg oppnår, så vet jeg at jeg ville bli lykkelig
- Hvis mine venner er ulykkelig så kan ikke jeg være lykkelig
- Alt må gå bra for at jeg skal bli lykkelig

Følelsen av å få som fortjent

- Hvis det er hindringer i min vei, så er det naturlig at jeg sint
- Ting burde alltid gå bra for meg
- Hvis jeg gjør de riktige tingene, burde folk anerkjenne dette
- Hvis jeg føler at jeg fortjener noe, så burde jeg få det
- Hvis jeg anstrenger meg veldig for å hjelpe andre, så burde andre gjøre det samme for meg når jeg trenger det
- Jeg skulle ikke måtte jobbe så hardt for å oppnå det jeg vil

I hvilken grad stemmer følgende påstander for hvordan du *vanligvis* er:

1 Jeg klarer alltid å løse vanskelige problemer hvis jeg prøver hardt nok.

Helt galt	Nokså galt	Nokså riktig	Helt riktig
☐ 1	☐ 2	☐ 3	☐ 4

2 Hvis noen motarbeider meg, så kan jeg finne måter og veier for å få det som jeg vil.

Helt galt	Nokså galt	Nokså riktig	Helt riktig
☐ 1	☐ 2	☐ 3	☐ 4

3 Det er lett for meg å holde fast på planene mine og nå målene mine.

Helt galt	Nokså galt	Nokså riktig	Helt riktig
☐ 1	☐ 2	☐ 3	☐ 4

4 Jeg føler meg trygg på at jeg ville kunne takle uventede hendelser på en effektiv måte.

Helt galt	Nokså galt	Nokså riktig	Helt riktig
☐ 1	☐ 2	☐ 3	☐ 4

5 Takket være ressursene mine så vet jeg hvordan jeg skal takle uventede situasjoner.

Helt galt	Nokså galt	Nokså riktig	Helt riktig
☐ 1	☐ 2	☐ 3	☐ 4

6 Jeg kan løse de fleste problemer hvis jeg går tilstrekkelig inn for det.

Helt galt	Nokså galt	Nokså riktig	Helt riktig
☐ 1	☐ 2	☐ 3	☐ 4

7 Jeg beholder roen når jeg møter vanskeligheter fordi jeg stoler på mestringsevnen min.

Helt galt	Nokså galt	Nokså riktig	Helt riktig
☐ 1	☐ 2	☐ 3	☐ 4

8 Når jeg møter et problem, så finner jeg vanligvis flere løsninger på det.

Helt galt	Nokså galt	Nokså riktig	Helt riktig
☐ 1	☐ 2	☐ 3	☐ 4

9 Hvis jeg er i knipe, så finner jeg vanligvis en vei ut.

Helt galt	Nokså galt	Nokså riktig	Helt riktig
☐ 1	☐ 2	☐ 3	☐ 4

10 Samme hva som hender så er jeg vanligvis i stand til å takle det.

Helt galt	Nokså galt	Nokså riktig	Helt riktig
☐ 1	☐ 2	☐ 3	☐ 4

Vi vil stille deg noen spørsmål om ditt forhold til bruk av internett og dine forventninger til behandlingen. Sett ring rundt svarene som passer for deg.

1. **Hvor ofte bruker du internett?**

   Daglig Ukentlig Månedlig Sjeldnere

2. **Hvordan er din holdning til å bruke et internettbasert selvhjelpsprogram?**

Svært negativ		Nøytral		Svært positiv
1	2	3	4	5

3. **I hvilken grad har du forventninger til at et internettbasert selvhjelpsprogram kan være til hjelp for dine depresjonsplager?**

Svært høye forventninger		Nøytral		Svært lave forventninger
1	2	3	4	5

4. **Hvor stor er sjansen for at du vil benytte deg av dette internettbaserte selvhjelpsprogrammet (MoodGYM)?**

   0% 10 20 30 40 50 60 70 80 90 100%

Appendix II

Interview Guide

Intervjuguide lege

DATO
STED
ERFARING FRA ALLMENNPRAKSIS
ALDER

Generell oppfatning:

-Fortell litt om din erfaring med deprimerte pasienter og møtet dem.
- Hvordan opplever du å få en deprimert pasient på kontoret?
- På hvilken måte håndterer du en slik pasient?
- Fortell om den siste deprimerte du hadde på kontoret (inkl. hvordan møtte, hva gjorde, kontakt).

Motivasjon:

-Hva fikk deg til å ta kurs i kognitiv terapi?/ Hvordan fikk du vite om MoodGYM?
-Beskriv hvordan har du har forsøkt å gjennomføre behandlingen?
-Var det noe som var motiverende for deg som lege ved bruk av kognitive teknikker eventuelt MoodGYM?
-Hvilke momenter i behandlingen mener du var viktigst? Hvordan påvirket dette framgangen i behandlingen?
-Hva har vært vanskelig/barrierer og hvordan eventuelt løste du det?

- Ønsket pasientene å prøve dette?
- Gjorde pasientene hjemmeoppgavene?
- Var det tekniske utfordringer?
- Var det tid nok i konsultasjonene?
- Passet det i en vanlig konsultasjon? Utdyp!
- Hva skal til for å prioritere tid til å sette seg inn i teknikkene/MoodGYM?
- Hva skal til for at du skal føle at du har satt deg godt nok inn i det?

Behandlingen

-Hva syntes du om å bruke CBT eller MoodGYM?
-Hvordan opplevde du som lege behandlingen med MoodGYM?
-Hvem tror du kan være aktuell for slik behandling? (Hva gjør at en pasient passer/ikke passer til denne behandlingen?)
-Omtrent hvor mange pasienter har du prøvd det for?
-Fortell om en situasjon du husker godt fra tiden du har forsøkt å bruke Moodgym-behandlingen? Hvorfor denne episoden?
-Måtte du gjøre noen praktiske endringer i konsultasjonene for å gjennomføre behandlingen? (Tidsbruk, sette opp til kontroll, andre ting).
-Gjorde du noen forberedelser før du gikk i gang med å bruke MoodGYM i behandlingen?
-Opplevde du noen endring i kontakten du fikk med din pasient? Enn den siste?
-Hadde du mulighet til å påvirke behandlingsopplegget? På hvilken måte? Forsøkte du å tilpasse behandlingen til din måte å møte pasientene på?
-Kan du fortelle om noe du liker spesielt med denne måten å behandle depresjon på?
-Hvis du skulle anbefale dette til en kollega, hva ville du framheve?
-Hvis du fikk være med å videreutvikle MoodGYM etter erfaringene du har gjort deg, hva ville du forandre, ta bort eller legge til?

-Har du brukt nettsiden www.msh.no?
- Hvilke andre behandlingsalternativer vurderer du?

Kvalitet og samhandling

-Har det at du har tatt et kurs i kognitive teknikker gjort at pasientene har fått en annen behandling enn før?
-Har din bruk av MoodGym gjort at pasientene har fått en annen behandling av deg enn før?
-Opplever du at kurset i kognitive teknikker har gjort at du har endret din bruk av spesialisthelsetjenesten?
-Har du endret din bruk av spesialisthelsetjenesten etter at du har tatt i bruk MoodGym?
- Kunne du tenkt deg et kurs i CBT og eventuelt MoodGYM eller et annet selvhjelpsprogram, og hva skulle det i så fall inneholde?

For de som ikke har brukt noe fra kurset

- Kan du forestille deg at du kunne tatt i bruk kognitive teknikker/MoodGYM?
- Hva ville du synes om å be pasienter jobbe med et selvhjelpsprogram hjemme?
- Hva tenker du om å bruke et internettprogram i behandling?
- Hva ville du synes om å bruke tid på MoodGYM i konsultasjoner?
- Tror du det ville passe inn i en vanlig konsultasjon?
- Beskriv hvordan har du har forsøkt å gjennomføre nye tiltak/ta i bruk ny kunnskap du har lært på tidligere kurs om andre tema?
- Hvordan opplever du at det er å komme i gang med noe nytt i din daglige praksis?

Avslutning

-Er det noe du har tenkt på som du vil tilføye?
-Er det noe jeg ikke har spurt om som du gjerne vil fortelle?

TUSEN TAKK