

Faculty of Health Sciences, Department of Psychology

Internet-based cognitive behavior therapy for depression

Effectiveness and patient experiences

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Abstract in English

Internet-based interventions for depression and other common mental health disorders have received an increasing amount of attention in the last two decades. Most commonly, interventions are based on cognitive behavioral therapy (Internet-based cognitive behavioral therapy; ICBT). ICBT may include various degrees and types of support, from no support at all, to automated e-mail support, low intensity or high intensity therapist support either by e-mail, phone or face-to-face. The Internet program studied in this thesis is MoodGYM, which is based on cognitive behavior therapy, is openly accessible online without therapist or e-mail support.

ICBT has potential as a means of both prevention and treatment of depression. It can offer a way of reaching a high number of people in population based preventive initiatives. Widespread distribution in larger populations does not allow for intensive support, otherwise this would compromise the advantages of Internet-based interventions (reaching a high number of people, anonymity, and independence of deliverer capacity). Thus, for prevention efforts, Internet-based prevention is mainly self-guided. Automated e-mail support, and even tailored, automated e-mails could possibly increase adherence and outcome in prevention interventions. In depression treatment, a weighty argument for using an Internet-based approach has been that it can potentially increase the availability of highly demanded treatment, and fill a current treatment gap where psychological treatment is wanted but often unavailable. In a treatment setting, where the target is a single person or a small group, therapist support is often provided.

The overall aim of this thesis is to evaluate the effect of ICBT using MoodGYM, as an a) openly accessible, self-guided intervention, and b) as a treatment for depression including therapist support. The specific aims of each paper were I) to investigate the effect of automated e-mails on the usage of MoodGYM in a sample of high school students; II) to

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study the effects of MoodGYM with face-to-face therapist support in a sample of depressed primary care patients; and III) to explore patient experiences with MoodGYM with face-to-face therapist support.

The first paper presents a study conducted in high schools that used MoodGYM as a mental health promotion program with automated e-mail support or no support. Students were to undertake the program unsupervised by teachers in their own time. The findings show that uptake of the intervention was low, with a high drop-out which was unaffected by e-mail support. The low rate of participation and adherence compromised analysis regarding intervention effects on mental health measures.

The second paper investigated the effect of ICBT using MoodGYM with face-to-face therapist support in depressed patients compared to a waitlist control group. The results favored ICBT at post-treatment with moderate to high between-group effect sizes on measures of depression (BDI-II), anxiety (HADS-A) and satisfaction with life (SWLS). The intervention effects partly sustained at 6-month follow-up.

The third paper presents an interview study exploring patients' experiences of helpfulness from ICBT using MoodGYM with face-to-face therapist support. The patients' accounts describe what helps alleviate symptoms as 1) their own agency seeking treatment and during treatment; 2) the role of MoodGYM as a source of relevant knowledge; and 3) the dialogue with the therapist for sharing thoughts and feelings, and receiving feedback and assistance in making use of MoodGYM.

Overall, the thesis does not provide support for the use of MoodGYM as a self-guided mental health promotion program among high school students, which would be highly dependent on individual motivation. The main challenges seem to be both to initiate use and supporting sustained usage. Based on previous research and the additional findings in the thesis, an intervention providing individual support targeted at high-risk individuals may be a

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preferred mode of delivery. If the program is delivered as a universal program to students, closer supervision is necessary, e.g. by a teacher in the classroom.

In line with previous studies, the thesis supports the effectiveness of MoodGYM with face-to-face guidance. ICBT may be a valid treatment option for primary care patients presenting with depressive symptoms in the mild to moderate range, who otherwise have poor access to psychological treatment. Practitioners providing ICBT should be aware of the dynamic interplay between patient agency, program content and therapist support. The findings may be interpreted within a learning conceptualization of ICBT, corresponding to emotional, cognitive and behavioral learning processes.

Sammendrag (Abstract in Norwegian)

Psykiske lidelser representerer et folkehelseproblem, og depresjon er blant de absolutt vanligste lidelsene. Norske retningslinjer for behandling anbefaler psykologisk behandling for milde til moderate av depresjoner, men tilgjengeligheten av slik behandling er svært begrenset.

Internettbaserte løsninger har i økende grad de siste tjue årene blitt anvendt innen behandling av vanlige psykiske lidelser som depresjon og angst. Det er utviklet en rekke programmer som vil hjelpe sine brukere å redusere symptomer og øke mestring, og det finnes nå en betydelig forskningslitteratur som viser effekten av slik behandling. Internettbasert behandling for depresjon og angst varierer blant annet med tanke på kontakt med en terapeut, fra ingen kontakt med en terapeut til høy grad av kontakt. MoodGYM er et slikt program som bygger på prinsipper fra kognitiv atferdsterapi, og som er fritt tilgjengelig på Internet..

Denne avhandlingen har tre formål: 1) å undersøke effekten av MoodGYM, som en åpen, brukerstyrt intervensjon i videregående skole, 2) å undersøke effekten av MoodGYM med ansikt-til-ansikt terapeutstøtte som behandling for depresjon og 3) å belyse brukernes egne erfaringer med terapeutstøttet MoodGYM som behandling for depresjon.

Artikkel I presenterer en studie som var rettet mot elever i videregående skole for å evaluere MoodGYM som helsefremmende tiltak for psykisk helse. Hensikten var å evaluere anvendbarheten av et slikt program til dette formålet og dessuten å undersøke effekten av automatisert e-post på gjennomføringsgrad/fracfall fra intervensjonen. Artikkel II presenterer en studie hvor MoodGYM var hovedkomponent i terapeutstøttet behandling av deprimerte pasienter henvist fra primærhelsetjenesten. Formålet var her å evaluere effekten av behandling på depresjons- og angstsymptomer og tilfredshet med livet. Artikkel III presenterer en kvalitativ intervjustudie som undersøker pasientenes erfaringer med behandlingen i studien fra artikkel II, med fokus på hva de opplevde som virksomt for sin depresjon.

I artikkel I fant vi en høy grad av frafall som ikke ble signifikant påvirket av e-postoppfølging. Det ble ikke funnet effekt på psykisk helse, noe som kan skyldes det store frafallet. I artikkel II fant vi at behandlingen med terapeutstøttet MoodGYM hadde god effekt på depresjons- og angstsymptomer etter avsluttet behandling, sammenlignet med en ventelistegruppe. Vi fant også at effekten vedvarte seks måneder etter endt behandling. I artikkel III viste resultatene til behandlingen som et dynamisk samspill mellom a) MoodGYM som kilde til relevant kunnskap og struktur for behandlingen, b) pasienten som primær endringsagent i behandlingen og c) relasjonen til terapeuten som arena for å dele følelser og erfaringer, samt fremme forståelse og bruk av terapeutiske verktøy fra MoodGYM.

Avhandlingen gir ikke støtte til bruk av en åpen, internettbasert intervensjon som helsefremmende tiltak blant elever i videregående skole, da dette i stor grad blir avhengig av elevens egen motivasjon. Den primære utfordringen er å få brukere til å gjennomføre programmet. Det kan, ut fra annen forskning og de øvrige funnene i avhandlingen, være støtte for en tilnærming hvor elever med forhøyet risiko eller symptomnivå får internettbasert program med individuell oppfølging, for eksempel fra skolens helsesøster.

Vi finner, i likhet med annen forskning, støtte for en behandling med terapeutstøttet MoodGYM for personer med depresjonssymptomer. Internettbaserte programmer med terapeutstøtte kan være et trinn i behandlingsskjeden for milde til moderate depresjoner for å øke tilgjengeligheten av virksom psykologisk behandling for denne pasientgruppen. Komponenter som kan være viktig er relevansen av informasjonen Internetprogrammet gir, muligheten for dialog med en terapeut og pasientens evne til å nyttiggjøre seg av ny kunnskap.

Abbreviations:

AUDIT: Alcohol Use Disorder Identification Test

BDI-II: Beck Depression Inventory II

BAI: Beck Anxiety Inventory

CBT: Cognitive behavioral therapy

CCBT: Computerized cognitive behavioral therapy

CES-D: Centre for Epidemiological Studies Depression scale

DUDIT: Drug Use Disorder Identification Test

GSE: General Self-Efficacy scale

HADS: Hospital Anxiety Depression Scale

IAPT: Improving Access to Psychological Therapies

ICBT: Internet-based cognitive behavioral therapy

MINI: Mini-International Neuropsychiatric Interview

NICE: National Institute for Health and Care Excellence (England)

RSES: Rosenberg Self-Esteem Scale

SWLS: Satisfaction with Life Scale

List of papers:

- I Lillevoll, K. R., Vangberg, H. C., Griffiths, K. M., Waterloo, K. & Eisemann, M. R. (2014). Uptake and adherence of a self-directed Internet-based mental health intervention with tailored e-mail reminders in senior high-schools in Norway. *BMC Psychiatry, 14*,14.
- 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.
- III Lillevoll, K. R., Wilhelmsen, M., Kolstrup, N., Høifødt, R. S., Waterloo, K., Eisemann, M. & Risør, M. B. (2013). Patients' experiences of helpfulness in guided Internet-based treatment for depression: Qualitative study of integrated therapeutic dimensions. *Journal of Medical Internet Research, 15*,6, e126.

1. Introduction

“I guess I should have reacted the way most of the other girls were, but I couldn't get myself to react. I felt very still and very empty, the way the eye of a tornado must feel, moving dully along in the middle of the surrounding hullabaloo.” Sylvia Plath, The Bell Jar

1.1 Depression

Depression represents one of the major health concerns of our time. It affects individuals and their families deeply, and has tremendous effects for the society (Wittchen & Jacobi, 2005). According to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), the core symptoms of depression include depressed mood and loss of interest, with a minimum duration of two weeks (American Psychiatric Association, 2013). In addition, at least five other symptoms must be present in order to fulfill the diagnostic criteria for a depressive disorder, such as increase or decrease of appetite; insomnia or hypersomnia; psychomotor agitation or retardation; fatigue or loss of energy; feeling of worthlessness or guilt; diminished ability to concentrate or indecisiveness; or recurrent thoughts of death. In addition, the symptoms cause significant distress or impairment for the individual, and cannot not be accounted for by substance use, medical conditions or bereavement.

There are two main ways of assessing depression, either using clinical interviewing or self-report scales. The first corresponds to the understanding of depression as a categorical phenomenon with distinct features as described in the diagnostic manual. Individuals either fulfill criteria of the diagnosis or not. Diagnostic interviewing (e.g. the Mini International Neuropsychiatric Interview) can be used to assess the presence of diagnosis, in the literature referred to as ‘clinical depression’. However, this approach ignores the finding that even subthreshold depression may cause marked impairment and suffering (Lewinsohn, Solomon, Seeley, & Zeiss, 2000). Alternatively and commonly employed in research, depressive

symptomatology can be assessed continuously, using psychometric scales with established cut-off scores that indicate severity (e.g. Beck Depression Inventory II (BDI-II), Center for Epidemiologic Studies Depression Scale (CES-D) or Hospital Anxiety and Depression Scale (HADS)).

Prevalence of depression in Norway is comparable to international estimates, although differences in methodology complicate direct comparisons. The estimated 12-month prevalence of major depressive disorder across Europe is 6.9 % (Wittchen et al., 2005; Wittchen, Jacobi, Rehm, Gustavsson, Svensson, Jönsson et al., 2011), thus, approximately 30 million people will suffer from depression during one year. Estimates of the 12-month prevalence of depression in Norway is 7.3 % among the adult population (Kringlen, Torgersen, & Cramer, 2001). Life-time prevalence, as estimated by the National Comorbidity Survey (NCS) Replication in the United States, is 16.6 % for major depression (Kessler, Berglund, Demler, Jin, Merikangas, & Walters, 2005). In a Norwegian sample of adults, life-time prevalence was 17.8 % (Kringlen et al., 2001). Among adolescents in the age of 13-17, the 12-month prevalence of depression or dysthymia is estimated to 8.2 % according to the NCS study (Kessler, Avenevoli, Costello, Georgiades, Green, Gruber et al., 2012), with a severity distribution fairly equally distributed into mild, moderate and severe problems (Kessler, Avenevoli, Costello, Green, Gruber, McLaughlin et al., 2012). A longitudinal study of development of depression found a life-time prevalence of depression and dysthymia at age 18 of 20.67 % (Hankin, Abramson, Moffitt, Angell, Silva, & McGee, 1998). The life-time prevalence of depression, dysthymia or depression not otherwise specified (NOS) in a Norwegian study of adolescents aged 14-16 years, was 23 % among adolescents (Sund, Larsson, & Wichstrøm, 2011).

Depression in childhood is rare, however, prevalence studies show that first onset often occurs during middle adolescence or early adulthood (Hankin et al., 1998). During childhood

the prevalence is similar for boys and girls, but gender differences become apparent in middle adolescence. Between the ages 16 to 18, there is an increase in prevalence for both genders, but a markedly sharper increase among girls (Hankin et al., 1998). This gender difference sustains through adulthood (Wittchen et al., 2005). Depression often follows a recurrent trajectory, with approximately sixty per cent of sufferers of a depressive episode will experience recurrent episodes (American Psychiatric Association, 1994; Solomon, Keller, Leon, Mueller, Lavori, Shea et al., 2000). The probability of recurrent episodes is influenced by the number of lifetime episodes, thus, the risk of recurrence increases for each successive recurrence (Solomon et al., 2000).

1.2 Preventing depression

The prevalence of depression and its recurrent nature highlight the need for preventive and early intervention efforts. Prevention efforts may be universal, including interventions aimed at a whole population group, selected, targeting subgroups of the population that are at risk, or indicated, targeting individuals with minimal symptoms or markers indicating a predisposition for the disorder (Mrazek & Haggerty, 1994)(pp.22-24). Considering the steep increase in depression rates during adolescence and the risk of recurrence (Hankin et al., 1998; Lewinsohn, Clarke, Seeley, & Rohde, 1994), the gains of successful preventive interventions targeting this group can be substantial.

Schools have become one of the most important settings for preventive interventions that aim for both enhancing resilience and reducing internalizing and externalizing problems (World Health Organization, 2004). Delivering preventive interventions in the school environment have advantages such as a highly structured setting and a potential of reaching a cross section of the normal population of adolescents. This includes reaching individuals across socioeconomic statuses, people in risk of depression, and the opportunity to impact on

knowledge about mental health issues and prejudice against people with mental health problems. On the other hand, extra-curricular activities can take up precious time and teacher resources, an issue that may prevent schools from implementing preventive interventions.

There are a number of depression prevention programs that vary in content, although most include some components of cognitive behavioral therapy (Merry, Hetrick, Cox, Brudevold-Iversen, Bir, & McDowell, 2012). Previous research has yielded mixed results regarding the effectiveness of depression prevention interventions among adolescents. A review by Jané-Llopis and colleagues (2003) found effect sizes ranging from low (-.10 and .11) to moderate (.75), with no overall difference between universal, selective and indicated programs, a finding supported by later reviews (Brunwasser, Gillham, & Kim, 2009). On the other hand, several reviews find targeted programs to outperform universal programs (Calear & Christensen, 2010; Horowitz & Garber, 2006; Stice, Shaw, Bohon, Marti, & Rohde, 2009) leading some authors to suggest prevention efforts should mainly focus on high-risk individuals (Stice et al., 2009). However, universal interventions delivered to all students within a school environment have benefits such as reduced stigma, no screening procedure needed to identify individuals at risk, and their continuous application for mental health promotion.

1.3 Depression treatment

There are numerous theoretical viewpoints regarding the individual vulnerabilities and development of depressive disorders and the mechanisms at work during depression. Theories operate at different conceptual levels and are not necessarily mutually exclusive, e.g. neurochemical, interpersonal, cognitive. Biological models seek to understand the genetic predispositions of depression, and its endocrine and neurochemical basis (Cleare & Rane, 2013). Interpersonal theories emphasize the social context in which depressive symptoms

develop and the social role and interpersonal relationships of the individual (De Mello, De Jesus Mari, Bacaltchuk, Verdeli, & Neugebauer, 2005). Depending on the assumed mechanisms of depression, each theoretical approach provides recommendations for treatment.

One of the most influential theories of depression is cognitive theory, which also makes assumptions about the recovery process of depression (Garratt, Ingram, Rand, & Sawalani, 2007). According to cognitive theory (Clark & Beck, 1999), depressogenic schemas are part of a diathesis-stress model of depression and fundamental to the development of the disorder. The concept of schemas appertains to long-held core beliefs about the self that may not be overtly accessible to the individual, but give rise to surface cognitions such as automatic thoughts. When individuals are exposed to stressors, these depressogenic schemas can be activated and lead to negative perceptual biases and thinking, which eventually can turn into a downward spiral towards depression (Garratt et al., 2007). Depressogenic schemas are only indirectly observable through depressive automatic thoughts, dysfunctional attitudes, negative attributional patterns and cognitive distortions.

The assumption of a biased information processing system lies at the core of the cognitive theory of depression etiology, maintenance and recovery (Clark et al., 1999). Cognitive theory postulates that improvement in depressive symptomatology depends on changes in the information processing system. Cognitive behavioral therapy (CBT) aims to alter the function of depressive schemas (Beck, Rush, Shaw, & Emery, 1979), making use of both cognitive and behavioral strategies (Allen, 2006). There is a substantial body of research supporting the effectiveness of CBT in treating depression with large effect sizes in outpatient samples (Hollon & Beck, 2013). There has been discussion regarding the effectiveness of CBT in severe depression, although evidence suggest CBT to be a viable treatment option (Hollon et al., 2013; Luty, Carter, McKenzie, Rae, Frampton, Mulder et al., 2007).

Furthermore, findings indicate a reduced risk of relapse following treatment termination in CBT compared to pharmacological treatment (Hollon et al., 2013)

1.4 Availability of treatment

According to the European Study of the Epidemiology of Mental Disorders (ESEMeD), an estimated 15 % of mood disorders remain untreated (12 months prevalence) (Alonso, Angermeyer, Bernert, Bruffaerts, Brugha, Bryson et al., 2004). This makes depression one of the disorders that more likely receive professional attention and treatment (Bijl, De Graaf, Hiripi, Kessler, Kohn, Offord et al., 2003). The majority of help-seeking individuals receive treatment in the primary health care services (Wang, Aguilar-Gaxiola, Alonso, Angermeyer, Borges, Bromet et al., 2007), and approximately 38 % are receiving pharmacological treatment only (Alonso et al., 2004). The clinical guidelines for depression treatment include counseling, psychotherapy and pharmacotherapy. Because of the poor risk-benefit ratio of pharmacotherapy in mild to moderate depression, antidepressants are not recommended initial treatment for this group of patients (National Institute for Health and Care Excellence (NICE), 2009; Helsedirektoratet, 2009). Counseling and psychological interventions should be the first choice in mild to moderate depression, even including novel treatment approaches such as self-help through Internet-based programs or bibliotherapy. According to clinical guidelines, more severely depressed patients should be offered a combination of antidepressants and structured psychological treatment.

There are some differences between European countries and health care systems regarding mental health service use, but the majority of patients with mood disorders receive treatment in primary care (Alonso et al., 2004). Services in primary care are limited to empathic listening, informal supportive therapy, prescription of antidepressants and referral to specialized services (Backenstrass, Joest, Rosemann, & Szecsenyi, 2007; Dalgard, Sjetne, Bjertnæs, & Helgeland, 2008). Pharmacotherapy is by far the most common intervention for

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depression (Alonso et al., 2004), although a review of the literature concludes that patients prefer psychological treatment (Van Schaik, Klijn, Van Hout, Van Marwijk, Beekman, De Haan et al., 2004). However, there is a shortage of trained therapists to deliver effective psychotherapy for depression in primary care and specialty mental health services (Lovell & Richards, 2000; Mykletun, Knudsen, & Mathiesen, 2009), and Norwegian general practitioners call for both increased capacity in secondary care and increased competence regarding depression treatment (Mykletun, Knudsen, Tangen, & Øverland, 2010).

Considering the fact that the majority of cases receiving treatment are mild to moderate, it is an intriguing paradox that the most frequently offered treatment is pharmacological. There is a need for means to improve access to psychological treatments in order to meet the demands. On the other hand, intensive psychological treatment puts a strain on limited resources in the health care system, and there is a need for low-intensity treatment options. A stepped-care model for treatment may provide a solution.

Stepped care model

Stepped-care models differentiate treatment options into lower and higher intensity treatments, offering the low intensity interventions initially, succeeding to higher intensity treatments when needed (Haaga, 2000). Pretreatment assessments and clinical judgment should inform treatment assignment to the minimum level intervention to achieve maximum gain (Newman, 2000; Scogin, Hanson, & Welsh, 2003). High intensity treatment commonly refer to weekly, face-to-face, one-to-one sessions with a trained therapist, whereas low intensity services consist of less clinician input but typically include self-help material that the patient works through.

The National Health Trust initiative Improving Access to Psychological Treatments (IAPT) offers an example of stepped-care for depression (Clark, 2011). Here, depression and anxiety disorders are treated within a stepped care model in line with NICE clinical

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guidelines. Patients may self-refer or be referred by their general practitioner. Low-intensive treatments for depression include self-help or computerized CBT combined with brief guidance of personnel trained in low-intensity interventions, psychological wellbeing practitioners. Overall, reports of year one data from 31 clinics find a mean reliable recovery rate at 40.3 % and reliable improvement rate at 63.7 %, when measured by both the Patient Health Questionnaire Depression Scale and the Patient Health Questionnaire Generalized Anxiety Scale (Gyani, Shafran, Layard, & Clark, 2013).

From a health policy and societal perspective, more efficient resource allocation is a weighty argument supporting the implementation of stepped care. Offering low intensity treatment as a first treatment option to individuals at an early stage could potentially reduce the burden of societal costs related to mental health problems. For the individual patient, receiving timely care can reduce suffering and support mastery.

In summary, depression is a highly prevalent, recurrent disorder, often with first onset in adolescence, with a large degree of unmet need and many cases remaining untreated. There is a lack of good measures to prevent the development of depression in adolescents. The majority of cases of depression being treated receive pharmacotherapy, despite its limited effects in mild and moderate depression. Access to effective psychological treatment is strained, although it is the preferred form of treatment among patients with depression. Internet-based CBT offers a low-intensive approach to depression prevention and early intervention.

1.5 Internet-based self-help interventions

More than two decades of research on Internet and computerized mental health interventions have sought to establish their effectiveness in reducing various emotional and behavioral problems, most commonly anxiety disorders, eating problems and depression (Marks,

Cavanagh, & Gega, 2007). The term 'computerized' interventions refers to treatment provided via a computer. This includes internet-based interventions, computers placed within a clinic or applications used at home computers. The term 'Internet-based' interventions refers to treatment delivered over the Internet, and is as such, an integral part of 'computerized' interventions. Such mental health interventions range from educational interventions with largely generic content, to therapeutic interventions with or without human support aimed at promoting positive changes in users (Barak, Klein, & Proudfoot, 2009). Key components that interventions vary across are a) the content of the program, b) use of multimedia, c) interactive online activities and d) provision of feedback. Therapeutic interventions are typically set up in modules meant to be fulfilled in sequence, most often once a week with a median duration of ten weeks (Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012). The content typically includes generic educational information, assessments of current problems and changes over time, content guiding users in making goals and action plans, suggesting techniques and providing homework (Marks et al., 2007). Most internet interventions draw on principles of cognitive behavioral therapy (CBT), an approach aimed at alleviating psychological suffering through targeting maladaptive cognitions and behaviors (Beck, Steer, & Brown, 1996). The structural nature of CBT is transferable to the format of Internet interventions, but there are interventions based on other types of therapy such as psychodynamic therapy (e.g. Johansson, Ekbladh, Hebert, Lindström, Möller, Petitt et al., 2012), problem solving therapy (e.g. Hoek, Schuurmans, Koot, & Cuijpers, 2012) and interpersonal therapy (e.g. Donker, Bennett, Bennett, Mackinnon, Van Straten, Cuijpers et al., 2013). Internet interventions can be accessible online at no or low cost or as commercial products without any form of interaction with a therapist (e.g. www.moodgym.edu.au, www.ecouch.edu.au; www.Deprexis.de), or can be integrated as part of regular mental health care services including therapist contact (e.g. Improving Access to Psychological

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Therapies, National Health Services, England; eMeistring, Bergen Health Trust, Norway; Internetpsykiatri.se, Karolinska University Hospital, Sweden), or at an online clinic (e.g. This way up clinic, Clinical Research Unit for Anxiety and Depression, Australia). Therapist support, when is provided, is often through e-mail, phone or face-to-face sessions (Kelders et al., 2012; Marks et al., 2007). Interventions delivered via the Internet have the advantages of being accessible to the user at any time and location, low costs for both the user, and for the service deliverer once the program software is developed.

1.6 Internet-based interventions for depression

A growing body of research on Internet-based and computerized interventions supports their effectiveness in reducing depressive symptoms among sufferers (e.g. (Christensen, Griffiths, & Jorm, 2004; Johansson, Sjöberg, Sjögren, Johnsson, Carlbring, Andersson et al., 2012; Perini, Titov, & Andrews, 2009; Ruwaard, Schrieken, Schrijver, Broeksteeg, Dekker, Vermeulen et al., 2009). Research on computerized treatments can be divided into two "branches" where studies within one branch provide some professional support to the patient during treatment (guided interventions), whereas studies in the other offer fully self-guided programs, except perhaps an initial assessment at baseline. Few studies have compared self-guided and guided interventions directly, and findings in such studies are mixed (Berger, Hämmerli, Gubser, Andersson, & Caspar, 2011; Farrer, Christensen, Griffiths, & Mackinnon, 2011; Sethi, Campbell, & Ellis, 2010). Meta-analysis has found large differences in effect sizes between studies of guided and self-guided interventions, favoring the former (Andersson & Cuijpers, 2009; Cowpertwait & Clarke, 2013). Still, the effects of self-guided interventions are found to be small but significant (Cuijpers, Donker, Johansson, Mohr, van Straten, & Andersson, 2011). Effect sizes for guided interventions are in the moderate to high range, 0.56-1.09, compared to the lower range, 0.02-0.55, in self-guided

intervention (Titov, 2011). It has been noted that possible differences in outcome may be due to poorer adherence in unguided studies, when less of the intervention material is experienced by the user.

A few studies have conducted direct comparisons between therapist supported computerized interventions and face-to-face therapy (Selmi, Klein, Greist, Sorrell, & Erdman, 1990; Wagner, Horn, & Maercker, 2014; Wright, Wright, Albano, Basco, Goldsmith, Raffield et al., 2005) and also a self-guided intervention to group face-to-face treatment (Spek, Nyklíček, Cuijpers, & Pop, 2008). The results are indicative of equivalent benefits of the treatments. Meta-analytic studies so far have not found outcome differences between face-to-face and computerized treatment for depression or anxiety (Andersson et al., 2009; Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010).

The majority of studies have tested computerized interventions in community samples, although some randomized controlled trials of depressed primary care patients have been conducted (e.g. (De Graaf, Gerhards, Arntz, Riper, Metsemakers, Evers et al., 2009; Hickie, Davenport, Luscombe, Moore, Griffiths, & Christensen, 2010; Salkovskis, Rimes, Stephenson, Sacks, & Scott, 2006). The findings are promising (Høifødt, Strøm, Kolstrup, Eisemann, & Waterloo, 2011), although some evidence support the effectiveness of such treatment in reducing symptoms of depression and anxiety (Proudfoot, Goldberg, Mann, Everitt, Marks, & Gray, 2003; Proudfoot, Ryden, Everitt, Shapiro, Goldberg, Mann et al., 2004), whereas others did not find outcome differences compared to treatment options (De Graaf et al., 2009; Salkovskis et al., 2006). Findings may indicate that computerized treatments are no more effective than usual care in patients with moderate to severe depression (De Graaf et al., 2009; Salkovskis et al., 2006). Observational cohort studies of guided self-help interventions in routine care add to the research using RCT design, and provide important knowledge about efficacy before large-scale dissemination. Few have

conducted such studies, but one Swedish study found a significant improvement in depression post-intervention and at 6-months follow up in a large sample of routine care patients (Hedman, Ljótsson, Kaldø, Hesser, El Alaoui, Kraepelien et al., 2014).

There are still unresolved issues concerning effectiveness of computerized treatment. A recent meta-analysis found support for a moderate post treatment effect of computerized CBT for depression, but cannot find significant long-term effects or even function improvement post treatment (So, Yamaguchi, Hashimoto, Sado, Furukawa, & McCrone, 2013). Other reports find sustained treatment effects after one year (De Graaf, Gerhards, Arntz, Riper, Metsemakers, Evers et al., 2011) and three years (Andersson, Hesser, Veilord, Svedling, Andersson, Sleman et al., 2013), and lower relapse rates at two-year follow-up (Holländare, A. Anthony, Randestad, Tillfors, Carlbring, Andersson et al., 2013).

Self-guided interventions

Self-guided Internet-based interventions are particularly suited for large-scale dissemination in the population or as a preventive measure among subgroups. There is evidence for positive outcome effects in population-based studies (Christensen, Griffiths, & Korten, 2002; Powell, Hamborg, Stallard, Burls, McSorley, Bennett et al., 2013), and such results seem to be consistent in spontaneous site users compared to trial participants (Christensen, Griffiths, Korten, Brittliffe, & Groves, 2004). A recurring issue in Internet-based intervention research, in particular regarding self-guided interventions, is the issue of attrition (Christensen, Griffiths, & Farrer, 2009; Eysenbach, 2005). Non-usage attrition rates in RCTs range from 1-50 % (Christensen et al., 2009; Cuijpers et al., 2011). For open websites non-usage attrition has been reported up to 99 % (Christensen, Griffiths, Korten, et al., 2004). Randomized controlled trials report better retention, i.e. sustained usage of the intervention, than open trials (Christensen, Griffiths, Korten, et al., 2004). This may be due to the structured setting of research trials compared to open websites with spontaneous users.

The use of "push" factors, such as e-mail reminders or telephone tracking, has been recommended to increase adherence in Internet-based interventions (Lintvedt, Griffiths, Sørensen, Østvik, Wang, Eisemann et al., 2013; McKay, Danaher, Seeley, Lichtenstein, & Gau, 2008; Neil, Batterham, Christensen, Bennett, & Griffiths, 2009; Nijland, Van Gemert-Pijnen, Kelders, Brandenburg, & Seydel, 2011). In a systematic review by Kelders and colleagues (2012), RCT design predicted better adherence, along with increased interaction with a therapist, more frequent intended usage, more frequent intervention updates and extensive use of dialogue support, such as reminders. Research findings to date are mixed concerning the effects of adding "push" factors. Farrer et al (2011) found no differences in adherence to an Internet-based intervention (MoodGYM) for depression between a group of participants receiving weekly 10 minutes of telephone tracking compared to a no tracking group. A meta-analysis of Internet-based treatment for depression yielded larger mean effect sizes for interventions using reminder systems (Hedge's $g = 0.49$ versus 0.24) (Cowpertwait et al., 2013). In health behaviour interventions for diet, weight loss and exercise, the use of periodic prompts is associated with positive results, although not entirely consistently (Fry & Neff, 2009). Reminders are frequently employed in Internet-based interventions, although approximately one fourth does not include reminders (Kelders et al., 2012). The optimal type and frequency of reminders in health interventions are yet to be determined (Cowpertwait et al., 2013; Fry et al., 2009).

1.7 How does ICBT work? – Potent factors of therapy

The effectiveness of computerized and Internet-based CBT as a treatment option for depression has been supported through a substantive body of research, as has been documented in the previous section. The mechanisms through which reduction in depressive symptoms is attained remains unclear, although some studies of predictors and moderators of

outcome in CCBT have been conducted. A number of patient characteristics have emerged as significant predictors within single studies, but a consistent pattern across studies is not eminent. Patient characteristics that have been associated with better outcome include female gender (Donker, Batterham, Warmerdam, Bennett, Bennett, Cuijpers et al., 2013), higher education (Warmerdam, Van Straten, Twisk, & Cuijpers, 2013), employment (De Graaf, Hollon, & Huibers, 2010) and marital status (Button, Wiles, Lewis, Peters, & Kessler, 2012). Psychological factors and variables related to illness severity have also been investigated with mixed results. Some studies find high pretreatment illness severity at baseline related to increased benefit (Button et al., 2012; Warmerdam et al., 2013), whereas others find no association with outcome (Donker, Batterham, et al., 2013; Farrer, Griffiths, Christensen, Mackinnon, & Batterham, 2013), or poorer response among individuals with more severe symptom level (Sunderland, Wong, Hilvert-Bruce, & Andrews, 2012). Possible psychological, mediating variables that may account for the relationship between CCBT and improvement in depressive symptoms have received some attention. Warmerdam and colleagues (2010) found a reduction in dysfunctional attitudes, worry, negative problem orientation and strengthened feeling of control following Internet-based CBT or problem-solving therapy (PST). Drawing on social learning theory, mental health self-efficacy, i.e. the belief in one's own ability to perform specific behavior, is proposed as a possible mediating factor. If so, targeting self-efficacy in online interventions can improve outcome, an assumption that has received preliminary support (Clarke, Proudfoot, Birch, Whitton, Parker, Manicavasagar et al., 2014).

Another line of psychotherapy research recognizes the context within which therapy is embedded, and assumes that factors common across therapies influence outcome (Frank & Frank, 1991; Norcross, 2002; Wampold, 2015). The working alliance is acknowledged as an important ingredient in face-to-face therapy (Horvath & Luborsky, 1993), and research into

the role of alliance in CCBT and ICBT is emerging. A study comparing guided Internet-based CBT and face-to-face CBT did find that strong working alliances could be established in both settings, and that alliance was moderately correlated to depression post-treatment (Preschl, Maercker, & Wagner, 2011). However, the findings were equivocal, as alliance ratings did not predict change in depression from baseline to post-treatment. Andersson et al. (2012) investigated the alliance ratings in guided ICBT and e-mail therapy across three studies on depression, generalized anxiety disorder and social anxiety disorder. In line with Preschl et al. (2011), there were overall good alliance ratings in both e-mail therapy and guided ICBT, with no significant relationship to depression and anxiety change scores. Similar findings were reported in a study among university students, in which online CBT was compared to e-mail CBT (Richards, Timulak, & Hevey, 2013). The mean alliance ratings were lower than in the studies by Preschl et al. (2011) and Andersson et al. (2012), but were unrelated to improvement on outcome measures. It has been suggested that working alliance might be less important in computerized treatments than face-to-face treatments (Andersson et al., 2012), or that mechanisms of change might differ in computerized and traditional face-to-face therapy (Cavanagh & Millings, 2013). The relationship between user/patient, program, and supporter/therapist needs further exploration to widen our understanding of possible change mechanisms, strengths and limitations of e-mental health interventions. The dyad between a computer program for depression and seven mildly depressed users was explored in an interview study by Purves & Dutton (2013). Salient aspects of the therapeutic process were the users' relationship to the program that fostered encouragement and motivation, and presumed trust in terms of confidentiality and credibility. Furthermore, working with the program helped users work with their depression by offering structure to make order of their inner world and stimulate new thinking, and increasing personal agency. Personal agency, or

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empowerment, is emphasized as one of the major assets of e-mental health interventions (Richards, 2004). Further research into the patient-program-therapist triad is warranted.

1.8 Aims of the thesis

Internet-based interventions have a potential within different approaches to depression prevention and treatment. The thesis comprises three separate studies with the overarching theme being effectiveness and experiences of helpfulness of an Internet-based intervention (MoodGYM) for reducing depressive symptoms. The potential of MoodGYM as a prevention and early intervention tool among youth were investigated in a study in high-schools. The specific aims were:

- a) To evaluate the use of MoodGYM as a prevention and early intervention means in high schools (paper I)
- b) To investigate the effect of automated e-mail reminders to promote sustained usage of MoodGYM (paper I)

A study of the effectiveness of guided self-help using MoodGYM for treatment of depression in primary care patients was undertaken, with the specific aim:

- c) To evaluate the effectiveness and acceptability of a treatment consisting of MoodGYM with face-to-face therapist support in primary care patients (paper II).

A study of depressed patients' experiences that might extend our understanding of the triadic relationship between patient-program-therapist, with the specific aim of:

- d) Undertaking an in-depth exploration of patient experiences with MoodGYM plus face-to-face therapist support, focusing on possible benefits or helpfulness of the treatment (paper III).

2. Method

“A question, by proposing a distinction, constructs its answer.” Keeney, 1983.

2.1 Introduction to Method

The following method section is divided into three parts corresponding to each of the studies that comprise the data material for this dissertation. The studies vary in their thematic and methodological stance, with the first two situated within the quantitative methodological tradition looking at the effects of the Internet-based program as an intervention measure, whereas the third explore the patient perspective using a qualitative approach.

Traditionally, quantitative methods of research emphasizing operationalization, objective measurement and controlled conditions have had a strong position in psychology. The randomized controlled trial has status as the golden standard for much psychological research, in particular that evaluating efficacy of treatment in clinical psychology (American Psychiatric Association, 2002; Norsk Psykologforening, 2007). This is parallel to the situation in medicine and psychiatry to which clinical psychology share common grounds and history (Benjamin Jr, 2005), with its emphasis on scientific method in positivistic terms. Qualitative methods of research aim to produce knowledge of social phenomena through exploring the subjective experiences of those involved (Malterud, 2003). It has the capability of bringing forth rich descriptions reflecting nuances and diversity provided in the data material. As such, qualitative study designs are valuable for gaining knowledge about patients' experiences with a treatment. Furthermore, they are well suited for exploring the dynamic process of human interaction fundamental to the practice of clinical psychology.

The studies of guided self-help using MoodGYM (paper II and III) combine the use of quantitative and qualitative methods, an approach labelled mixed methods. At the outset, the project was designed to include both approaches, with the purpose of generating a rich material to assess the treatment. In that sense one can say that they were of equal significance

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and complementary to each other. On the other hand, the inevitable methodological divergences force the researcher to prioritize one at the stake of the other. The application of quantitative methods, by conducting a randomized controlled trial, puts forward certain demands that decidedly were prioritized, such as standardized procedures for recruitment, selection, randomization, treatment and assessments. This makes up the foundation of the study, but is not how treatment in an everyday, routine care setting would proceed. From the perspective of qualitative methods, one might argue that the study would be better informed by a naturalistic setting. Hence, one can argue that the qualitative study under these circumstances is embedded within, and supplementary to, a quantitative trial. An alternative approach might include an independent qualitative study of guided self-help provided within a routine care setting. Given the aim of the current study, - to explore narratives of how guided self-help with MoodGYM might alleviate depression, it was deemed sufficient as a first investigation. A study within a naturalistic setting might have yielded some different results, given that the participants in a randomized controlled trial are dissimilar from the common routine care patient.

The studies that comprise this dissertation were conducted within different projects and data collection procedures, with one overarching theme: using MoodGYM to prevent and provide early intervention for depression. Study I was performed in high-schools in Troms county, Norway, and aimed to evaluate self-directed use of MoodGYM as a depression prevention measure. The purpose of study II was to assess guided self-help with MoodGYM for depression, before doing a naturalistic study among medical doctors in general practice. Study III is a qualitative study in which participants from study II were interviewed about their experiences from treatment.

The design, method and procedure of the different studies will be presented in the following.

2.2 Study I

The study was conducted from September to November 2009 in four high-schools in Troms county, Norway. All schools in the county were invited to participate in the study, but several were already involved with other mental health interventions or declined for other reasons.

The following section presents the design, participants, procedure and measures briefly. An expanded description is presented in paper I.

Design

The study was a four-arm randomized controlled trial with measures administered at baseline and post-intervention after 6-7 weeks. Totally there were three intervention groups and a control group: 1) MoodGYM without e-mail reminders; 2) MoodGYM with standard e-mail reminders; 3) MoodGYM with tailored e-mail reminders, and 4) a control condition similar to a waitlist control group, receiving information on how to access MoodGYM by the end of the trial. Originally, the trial included a 6-month follow-up to evaluate longer term prevention effects. However, this was omitted due to a low uptake and usage of MoodGYM in the intervention groups.

Participants and recruitment procedure

The participants were students in the volunteering schools, which the research group recruited through school visits. The students were between 15 and 20 years of age. All students were eligible for participation in the study.

The recruitment process included a short initial lecture about mental health and a presentation of MoodGYM, followed by an invitation to participate in the study. Students could, depending on their preference, either choose to participate in the baseline survey only, or in the MoodGYM trial, as well.

Procedure

The baseline survey was undertaken on the day of the research group visit. Participants consenting to the MoodGYM trial were randomly allocated to either one of the three intervention groups or the control group. The intervention groups received an e-mail within a week of the school visit containing information on how to log on to MoodGYM. Participants then used MoodGYM in their own time. The intervention groups, including reminders got weekly e-mails preceding each module of MoodGYM. Otherwise the intervention was unguided. By the end of the six weeks trial period, the research group visited the schools to collect post intervention data.

Materials

The baseline survey included questions about demographic characteristics (gender, age, average grade in high school) as well as self-reported current and previous need of help for psychological problems and mental health service use. Both the baseline and post intervention questionnaire included measures of depression (Centre for Epidemiologic Studies Depression Scale; CES-D, (Radloff, 1977, 1991)); self-efficacy (General Self-Efficacy scale; GSE (Leganger, Kraft, & Røysamb, 2000; Røysamb, Schwarzer, & Jerusalem, 1998)) and self-esteem (Rosenberg Self-Esteem Scale; RSES, (Rosenberg, 1965; Von Soest, 2005)). The post intervention questionnaire also included questions regarding reasons for non-usage of MoodGYM during the trial period. The questionnaires also included measures of depression stigma, personality, coping and substance use, not relevant for the current study.

Statistical analysis

The evaluation of the intervention included analysis of intervention effects, intervention uptake and effects of automated e-mails on adherence. Effects of the intervention on depressive symptoms and self-esteem were tested in the sample as a whole and in a subsample of participants with elevated symptoms ($CES-D > 16$) using a multivariate analysis of

variance. A possible association between intervention uptake and self-reported current need of help and automated e-mails were analysed using logistic regression analysis, testing whether the two latter variables could predict uptake. An ordinal regression analysis was used in order to test whether automated e-mails could increase adherence.

2.3 Study II

The study was conducted from November 2010 to December 2012 in the municipality of Tromsø. It aimed to be an initial evaluation of guided self-help with MoodGYM, before setting out to do a naturalistic study in general practice. The intervention required attendance to sessions at the clinic, thus, participants had to live in Tromsø or the surrounding area. In the following, the study design, participants, procedure and measure are presented briefly.

Expanded descriptions are presented in paper II.

Design

The study was a randomized controlled trial including an intervention group and a waitlist control group. The control group commenced treatment after the waiting period of seven weeks.

Participants and recruitment procedure

Participants were recruited via general practice clinics in Tromsø. The patient would submit the consent form to the researchers by mail, not needing to involve their doctor in their decision. The purpose was to ensure a proper, informed and autonomous consent, avoiding any perception of pressure from the doctor. However, experience from the trial showed that in some cases the consent was to some degree influenced by the doctor due to a lack of other treatment options.

Procedure

Potential participants were invited to a screening session in the clinic. The session lasted approximately for one hour and included the patients' problem presentation, a clinical interview (Mini-International Neuropsychiatric Interview; MINI (Sheehan, Lecrubier, Sheehan, Amorim, Janavs, Weiller et al., 1998)), questionnaires measuring depression (Beck Depression Inventory; BDI-II (Beck et al., 1996)), alcohol and substance use (Alcohol Use Disorders Identification Test; AUDIT, (Saunders, Aasland, Babor, De la Fuente, & Grant, 1993) and Drug Use Disorders Identification Test; DUDIT, (Berman, Bergman, Palmstierna, & Schlyter, 2005)), and recording of demographic variables and medication use. In line with recommendations to include a clinically representative sample in randomized controlled trials to enhance ecological validity (Hollon & Wampold, 2009; Sartorius, Ustün, Lecrubier, & Wittchen, 1996), it was decided not to exclude persons currently on antidepressant medication or participating in other non-CBT treatment. Patients currently on antidepressants were eligible for participation when medication could be considered as stabilized after 4 weeks. Furthermore, co-morbid conditions are common in primary care samples (Sartorius et al., 1996), thus only conditions that were in need of immediate attention or will substantially reduce the individuals' ability to participate in a self-help intervention lead to exclusion from the trial, i.e severe depression and suicidality, severe substance abuse or psychosis.

Patients eligible for participation were randomized to the intervention or control group. The intervention included homework with MoodGYM and sessions between each module. The purpose was to have weekly sessions, but delays were allowed. The sessions included a) evaluation of current symptom level, also with BDI-II, b) discussion of homework and c) preparation for the next module. Each session was scheduled to last between 15-30 minutes. The final session included post-test questionnaires, administered by a research

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assistant blind to the allocation assignment of participants. At 6-months post treatment, a follow-up data were collected via online survey software.

Measures

The Beck Depression Inventory (BDI-II) was the primary outcome measure (Beck et al., 1996) administered at every session. Secondary outcome measures were the Beck Anxiety Inventory (BAI, (Beck & Steer, 1993); Hospital Anxiety and Depression Scale (HADS, (Zigmond & Snaith, 1983), Satisfaction With Life Scale (SWLS, (Diener, Emmons, Larsen, & Griffin, 1985) and a measure of quality of life - the EuroQol Group 5-Dimension Self-Report Questionnaire (EQ-5D; (EuroQol Group, 2013). These were administered at baseline, post treatment or waiting (for control group) and at 6 months follow-up.

Statistical analysis

The effectiveness of the treatment was assessed by performing linear mixed models analysis of primary and secondary measures, and analyzing the clinically significant change on the primary measure.

2.4 Study III

The purpose of conducting a qualitative study of participants' experiences with guided self-help with MoodGYM was to explore experiences of helpfulness in the treatment of depression. The efficacy of the treatment compared to a control condition was to be investigated deductively in study II. However, what is helpful may not be fully explored in randomized controlled trials, helpfulness as we experience it may refer to more than mere symptom reduction as measured by psychometric scales. Thus, it was also eligible to obtain a richer description of experiences from people entering the treatment. We set out to collect participants' narratives of being in treatment, which in turn can expand our knowledge and

contribute to further development and practice of self-help. The phenomenological hermeneutical method was regarded suitable to this end.

Phenomenological hermeneutical method

The practical and analytical parts of the study were guided by the phenomenological hermeneutical method outlined by Lindseth & Nordberg (2004) for researching lived experience. It draws on the methodology of phenomenology with an emphasis on elucidating the meanings of lived experience through hermeneutics, i.e. the interpretation of text material.

Phenomenology is a philosophy (Van Manen, 1990) or methodology (Carter & Little, 2007) oriented towards a person's unique experience, trying to grasp the nature or meaning of phenomena, catching the invariable across variations. Phenomenology does not try to explain or seek to make inferences about the world, rather it offers insights and a deeper understanding of everyday phenomena that brings us in touch with the world, through the lived experience of human beings. At the core of phenomenology is the theory of intentionality, the inseparable connection between consciousness and the world, and the fact that human consciousness always has direction, - it is conscious of something. The lived experience is the subject matter of phenomenology, acknowledging that the world is only available to us through our conscious experience of it (Van Manen, 1990). Phenomenological research, similarly to other approaches in qualitative research, does not expect the enquirer to be a "blank slate" or an objective observer to the phenomena of interest. In studying the nature of phenomena, our preexisting assumptions and understandings, referred to as our natural attitude, need to be explicated (bracketing), and our perspective must be opened up (taking on a phenomenological attitude), in order to be able to describe the phenomena outside of one's own knowledge of it.

Narratives of peoples lived experiences gives access to their inner world and how they begin to move away from depression. These narratives obtained from interviews must be

fixed in text and subjected to analysis. Hermeneutics provide us with theory of text interpretation. Ricoeur (1976) relates language and the lived experience that occupy phenomenologists. Experiences are private and cannot be transferred to another person, but its' meaning can be transferred and become public through language and communication. "Language is the exteriorization thanks to which an *impression* is transcended and becomes an *ex-expression*" (p.19, italics added). The dynamic of interpretative reading is theorized as a circular process, moving between the text as a whole and its' parts. Understanding the text as a whole implies guessing its' meaning, which then is explained and validated through structural analysis of its parts. The phenomenological hermeneutical method of Lindseth and Norberg (2004), inspired by Ricoeur`s theory of interpretation, reflect this movement from the whole of a text, to its parts, and again a comprehensive understanding of the whole.

Relation to the research topic

This study were closely linked to study II in this thesis, as all informants were recruited from and during the course of the clinical trial in which I, the author of this thesis, acted as both researcher and therapist together with a close colleague (Høifødt). Although the process of research in all circumstances are influenced by the motivation, interests and knowledge of the researcher, this dual role as both researcher and therapist warrants particular awareness of one`s own position in relation to the research topic. Although limited clinical experience at the outset of this study, my background as being trained in clinical psychology, with an emphasis on cognitive behavioral therapy, has taught me about the importance of the therapeutic alliance and other common factors of therapy, as well as the specific therapeutic ingredients. The role as a therapist in the clinical trial in study II surely provided inside information that would influence the preconceptions concerning the research topic of the present study, which has the possibility to hinder or enrich research. On one hand, it could be considered a bias to the research, particularly if the preconceptions pass unnoticed in the mind

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of the researcher and shape the questions posed in the interviews, influence the interaction with participants during the interview and the interpretations of interview transcripts. On the other hand, at its' best, such in-depth knowledge can enrich the process of research, for instance through asking relevant questions and follow-up questions to participants.

Nevertheless, awareness and critical reflection of our preconception is essential to limit the influence of it on the data collection and analysis.

Interview protocol

The interviews were semi structured, guided by a protocol covering their general experience of the treatment and various themes of interest. The participants were asked to reflect upon their experiences of treatment motivation, experiences during treatment and changes in their lives related to depression or the treatment. The interview protocol is included in appendix 1.

Data collection and participants

The participants in the present study were recruited during the clinical trial in study II. The participants received oral and written information about study III and an invitation to participate in their final consultation with the therapist. Recruitment was continuous until the desired, pragmatically reasoned number of 14 participants was reached. The recruitment was strategic in the sense that it included both genders, participants in various age ranges and both treatment completers and non-completers. It turned out difficult to recruit non-completers, as many were unavailable after ending treatment prematurely, hence, the sample of informants mainly consist of treatment completers. Interviews were conducted by either the author of this thesis (interviews 8-14) or a colleague (M. Wilhelmsen, second author of the study III publication; interviews 1-7), and lasted for approximately 60 minutes. The author of this thesis, also being a therapist in the clinical trial, did not interview her own patients. Interviews were recorded and transcribed verbatim by either the first or second author or a research assistant. The initial coding procedure comprised separate coding by the first and second

author and the supervisor in this particular study (M. Risør) which was subsequently checked for consensus. The process of data analysis, from initial coding through to the extraction of themes was subject to discussion and reflection among the researchers (Lillevoll, Wilhelmsen and Risør).

The characteristics of the participants are summarized in table 1.

Table 1

Gender, age, depression severity at baseline, treatment outcome, modules completed and number of consultations in interviewees.

	Gender	Age	BDI-II diagnosis (BDI-II score)	Outcome (BDI-II score)	Completed MoodGYM	Number of consultations
1	Female	26	Moderate (22)	Recovered (7)	Yes	8
2	Male	26	Moderate (23)	Recovered (14)	Yes	8
3	Male	48	Mild (17)	No change (15)	Yes	9
4	Female	56	Mild (19)	No change (15)	Yes	9
5	Female	36	Moderate (25)	No change (18)	Yes	9
6	Female	22	Moderate (25)	Recovered (14)	Yes	8
7	Male	51	Moderate (22)	Recovered (5)	No	8
8	Female	28	Mild (15)	No change (16)	No	3
9	Male	26	Moderate (22)	Recovered (4)	Yes	8
10	Male	33	Moderate (28)	Recovered (5)	Yes	11
11	Female	39	Minimal (11)	Improved (5)	Yes	8
12	Female	61	Minimal (13)	Recovered (2)	Yes	8
13	Female	41	Minimal (10)	No change (7)	Yes	8
14	Female	44	Mild (14)	No change (15)	No	6

Id: K1-7 = first author interview, M1-7 = second author interview. BDI-II = Beck Depression Inventory-II

Analysis

Guided by the method outlined by Lindseth and Norberg (2004), analysis of the interview transcripts began with a naïve reading, in which one opens up ones' perspective and switching from a natural attitude to a phenomenological attitude. A naïve understanding, or in Ricoeurs terminology – a guess, of the meaning of the text is formulated. The structural analysis was conducted by dividing the text into meaning units, which are then condensed. The condensed

meaning units form up themes and sub-themes based on their similarities and differences. The naïve reading and structural analysis is part of a circular process in which the former is repeated if the latter invalidates the naïve understanding. The resulting interpretation of the text in terms of themes, are then reflected on in relation to context, e.g. associations with relevant literature.

3. Summary of results

3.1 Paper I: Uptake and adherence to a self-directed Internet-based mental health intervention with tailored e-mail reminders in senior high school students in Norway

Aim: The aims of this study were a) to evaluate the feasibility of disseminating a self-directed Internet-based mental health intervention (MoodGYM) in senior high schools, and b) to investigate possible effects of tailored e-mail reminders on initial uptake and adherence.

Method: 707 students were randomized into four groups: 1) tailored weekly e-mail reminders (n = 175), 2) standard weekly e-mail reminders (n = 176), 3) no e-mail reminders (n = 175) and 4) control group (n = 180). Logistic regression was used to test for effects of e-mail and self-reported need of help on initial uptake. Ordinal regression was used to test for effects of weekly e-mails on adherence to the intervention.

Results: There was a low initial uptake of the intervention (8.54 %) and a substantial non-usage drop-out. Tailoring e-mails did not significantly predict uptake, nor did weekly reminders predict adherence. Having a higher average grade in high-school predicted initial uptake.

Discussion: Disseminating a self-directed Internet-based intervention among high-school students proved difficult due to substantial non-usage. Alternative strategies of increasing interest, involvement and commitment in students might have increased uptake. Guided interventions rather than self-guided approaches may be a more suitable model for delivery of mental health interventions to adolescents.

3.2 Paper II: The clinical effectiveness of web-based cognitive behavioral therapy with face-to-face therapist support for depressed primary care patients: Randomized controlled trial.

Aim: The aim of this study was to evaluate the effectiveness and acceptability of a therapist supported Internet-based intervention (MoodGYM) for mild to moderate depression.

Method: 106 participants recruited from primary care were randomized into an intervention group or a delayed treatment group. Treatment comprised 6 weeks Internet-based cognitive behavioral therapy, weekly brief consultations with a clinical psychologist and e-mail reminders. Primary outcome measures was depressive symptoms measured by Beck Depression Inventory-II (BDI-II). Secondary outcomes were Beck Anxiety Inventory (BAI), Hospital Anxiety and Depression Scale (HADS), Satisfaction with Life Scale (SWLS) and quality of life measured by EuroQol Group 5-dimension Self-Report Questionnaire (EQ-5D). All outcome measures were based on self-report at baseline, post-treatment and 6-month follow-up. Linear mixed models were used to test for treatment effects.

Results: There was a significant difference in time trends between the groups on the BDI-II, HADS depression and anxiety subscales and SWLS. There were no differences between the groups on the BAI and EQ-5D. Significantly more participants recovered from depression in the intervention group compared to the delayed treatment group. Treatment effects on depression and anxiety were largely sustained at 6-month follow-up, and gains in satisfaction with life were partly sustained. Sixty per cent of the intervention group adhered to the program, and overall treatment satisfaction was high.

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Discussion: MoodGYM combined with brief therapist support can be effective in alleviating symptoms of depression and anxiety in primary care patients. Adherence rates and treatment satisfaction indicate treatment acceptability. This treatment has the potential to be implemented in routine care within a stepped-care approach, but still remains to be tested in regular primary health care.

3.3 Paper III: Patients' experiences of helpfulness in guided Internet-based treatment for depression: Qualitative study of integrated therapeutic dimensions

Aim: The aim of this study was to explore participants' experiences of being in ICBT treatment with a focus on the treatment dimensions that they considered helpful.

Method: We interviewed 14 participants in a randomized controlled trial testing an intervention featuring an Internet-based CBT program (MoodGYM) and brief supportive consultations with a therapist (paper II). Choosing a phenomenological-hermeneutical approach we sought to elicit their understanding of helpful dimensions in this treatment.

Results: The analysis identified five themes relating to meaning of this mode of treatment in terms of helpfulness. Two related to treatment in general: 1) Taking action to address one's problems, and 2) the value of talking to a professional. Two themes addressed this particular treatment with MoodGYM: 3) acquiring relevant knowledge, and 4) restructuring new knowledge acquired through MoodGYM. A fifth theme concerned 5) actual changes in patients' perceptions and interactions, following their experience with either MoodGYM or consultations with the therapist.

Discussion: The findings pointed to 1) the role of MoodGYM as a source of new and relevant knowledge, 2) the patients' role as the primary agent of change through adapting acquired knowledge from MoodGYM to their specific situation, and 3) the dialogue with the therapist as a trusting relationship in which to share thoughts and feelings, receive feedback and advice, and assisting the patient in making use of the MoodGYM content.

4. General discussion

4.1 MoodGYM in high-schools

The purpose of study I was to evaluate the use of MoodGYM as a self-directed intervention program for students in high school, mainly aiming at preventing and reducing depressive symptoms and strengthening self-esteem. The results did not find changes in the desired directions regarding depressive symptoms or self-esteem. Previous studies of prevention interventions for depressive symptoms in adolescents have yielded mixed results. Overall, there are some studies providing support for the effect of universal programs (Jané-Llopis et al., 2003; Merry et al., 2012), but recent rigorous studies have failed to replicate these findings (Araya, Fritsch, Spears, Rojas, Martinez, Barroilhet et al., 2013; Stallard, Phillips, Montgomery, Spears, Anderson, Taylor et al., 2013), or they find effects limited to high-risk subgroups (Kindt, Kleinjan, Janssens, & Scholte, 2014). The interventions studied are mainly based on CBT and were delivered in classrooms by teachers or trained personnel, but they were not Internet-based. Findings from studies using Internet-based programs for depression in schools are inconsistent, ranging from no significant effect (Wong, Fu, Chan, Chan, Liu, Law et al., 2012) to small or moderate effects (Calear, Christensen, Mackinnon, Griffiths, & O'Kearney, 2009; O'Kearney, Gibson, Christensen, & Griffiths, 2006; O'Kearney, Kang, Christensen, & Griffiths, 2009). It should be noted that Internet-based interventions in previous studies have been administered in classrooms, led by either a teacher or other personnel, whereas the intervention in the current study was self-directed. Considering the inconsistent findings in school-based and Internet-based depression prevention, the results of this study adds to the evidence casting doubt over the potential usefulness of this approach.

The lack of intervention effects can be explained by the high non-usage attrition rate in the trial, compromising the power of the study and hence the ability to detect smaller differences. However, the non-usage attrition is a finding in itself, with approximately 8.5 %

(45/527) of all participants logging on to MoodGYM, and only 9.6 % (19/198) of participants with elevated depression scores. This occurred, despite the fact that two intervention groups were receiving weekly e-mail prompts, even with tailored messages for one group. Presuming that the e-mails were read by the participants (one cannot rule out the possibility of e-mails being stopped by spam filters or adolescents rarely checking their e-mail account), one can conclude that the e-mail prompts did not enhance uptake or adherence.

One explanation for the low usage might be that adolescents themselves do not recognize symptoms as signs of depression, an explanation as to why help-seeking is low in this group, as reported in previous studies (Gulliver, Griffiths, & Christensen, 2010). This is a challenge for self-guided interventions in general, - how to reach the individuals in need. The e-mails were intended to promote the use of the Internet program, and tailoring e-mails were particularly aimed at making at-risk individuals aware of the potential relevance of the program, but this approach was unsuccessful. Another likely explanation to the non-usage attrition is that students perceiving themselves in need of help prefer informal sources of help, such as friends and family (Rickwood, Deane, Wilson, & Ciarrochi, 2005). Furthermore, Internet-based interventions may still be disadvantaged by a lack of knowledge of possible benefits (Bradford & Rickwood, 2014) causing reluctance to usage.

Possible implications

The poor adherence among all participants, as well as among those with elevated scores, raises the question if there is sufficient motivation among high school students for an Internet-based depression program. A universal delivery for Internet-based programs will inevitably be dependent on individual motivation and perceived benefit. In this study 83.23 % indicated that they *did not* have a current need for help due to psychological or social issues. The majority of students will not be presently depressed (2-month prevalence of adolescent depression in Norway being 9.3 % (Sund et al., 2011)), and most will not develop a

depression by the time they finish high school (life time prevalence at age 19 is 28 % (Lewinsohn, Rohde, & Seeley, 1998)). What would be the perceived benefit of undertaking a depression prevention program for this majority of students? The MoodGYM program is based on principles of cognitive behavioral therapy and focuses on depression and, to some extent, anxiety. According to the cognitive theory of depression, depression is related to depressogenic schemas activated by stressors, and which may not be overtly accessible to the individual ready for inspection and testing. It may be unrealistic to expect healthy students to commit to a CBT program for depression, considering that depression and negative thinking bears little reflection to them. It is an ethical consideration as well, if one should initiate large-scale universal prevention programs with mixed empirical support, taking up precious teacher and student time. Programs focusing on risk factors at an individual level, such as cognitive patterns, might serve well as targeted or indicated interventions embedded within the school environment. They can be administered by teachers or local school nurses who have the possibility to provide individual follow-up. Such an approach draws on the benefits seen in research on guided self-help with lower attrition rates and better outcomes.

It is still an unresolved question whether universal efforts for preventing depression in individuals through principles of CBT are worth the cost and effort, or what the optimal way to reach out to youth is. Research to date has yielded mixed results, but cautiously points in favor of targeted interventions. Internet-based programs can be suitable to this purpose, as they are associated with low levels of stigma and high availability. However, as our study shows, elevated levels of depressive symptoms may make people interested in Internet-based prevention and treatment, but they will not necessarily be motivated to sustained use of a program. Internet-based programs have the possibility of tailoring the content to the needs of the user, and thereby enhancing the relevance of information provided and the motivation of users.

Internet-based depression prevention in high schools should in addition rely on teachers, counsellors or school nurses to support uptake and sustained usage of the program. Communication could be solely web-based if an appropriate platform is developed and tested, or the nurse may schedule short follow-up sessions. School nurses in Norway often serve several different schools and can only be present on the premises a limited time, thus, web-based communication can be feasible and practical for supporting usage, but this remains to be tested.

4.2 Guided self-help with MoodGYM

Study II focused on the potential of MoodGYM as a low-intensive intervention that could be offered by doctors in general practice without extensive training in CBT. The study aimed to be a first step to assess the effect of MoodGYM with face-to-face sessions within a context similar to that of primary care. Firstly, a brief summary of the main strengths and limitations of the study are reviewed, before discussing the results of the study.

The study sample was relatively heterogeneous, including people with subclinical levels of depression as well as moderate to severe levels, and with various comorbid diagnoses (anxiety disorders were most common). The diversity of the sample was ensured by the broad inclusion criteria, with the purpose of increasing the generalizability of the findings to general practice populations. The treatment was designed to fit into the context of primary care, which could be offered as a structured, time-limited intervention within a stepped-care approach. These are characteristics that strengthen the external validity of the study, and the findings merits further efforts to research Internet-based treatment in routine care.

There are questions concerning possible sources of bias, that is, issues that threaten the internal validity of the study. As these are discussed thoroughly in paper II they will only be briefly recaptured here. Some main problems include lack of placebo control, lack of blinding

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and researcher allegiance. The design of the study does not control for placebo effects, although this could have been possible, albeit difficult. It is not common for studies on Internet-based interventions or psychotherapy to have placebo control groups, due to the fact that a mock treatment is difficult to create (Hollon et al., 2009). Rather, new treatments are compared to established treatments known as effective, or, as in this study, compared to a wait list control to establish whether the treatment outperforms “nothing”, i.e. spontaneous recovery. Although the control group in the current study did not receive entirely “nothing” (they did have the screening consultation with their therapist) it cannot be ruled out that a substantial placebo effect influence the results.

The next issues, lack of blinding and researcher allegiance are related, and caused by pragmatic and resource conditions. The lack of blinding therapists (the author of this thesis and first author of paper II) to group allocation may unintentionally have affected the treatments given to the intervention and the control groups, and hence have biased the results. Furthermore, it is well known that researcher allegiance can influence the results of studies in favor of the experimental treatment (Hollon et al., 2009).

Effects of the treatment

Given the limitations of the study, the results are modestly encouraging. There were significant improvements in depressive symptoms (BDI-II and HADS), anxiety (HADS) and satisfaction with life (SWLS). Table 2 gives an overview of effect sizes for measures of depression in paper II and studies relevant for comparison. Regarding the primary outcome, both the intervention group and the control group reported decline in depressive symptoms from pre- to posttest. The decrease in the control group can be explained by spontaneous improvement, or the screening consultation before group allocation may have had an impact. The within-group effect size in the intervention group is considered large, although lower than other studies (see table 2), (Johansson, Sjöberg, et al., 2012; Perini et al., 2009; Wagner et al.,

2014). At follow-up, the BDI effect size is still large, although it is considerable lower than effect sizes reported in other studies (Johansson, Sjöberg, et al., 2012; Wagner et al., 2014).

The between-group effect size is considered in the medium range, which is in accordance with other studies using control groups for comparison, but somewhat below average for other studies (see table 2), (Christensen, Griffiths, & Jorm, 2004; Farrer et al., 2011; Ruwaard et al., 2009). The relatively low between-group effect size may be explained by the decline in BDI-II scores in the control group. Early studies of Internet based or computerized CBT with primary care patients, yielded moderate effect sizes (Cavanagh, Shapiro, Van Den Berg, Swain, Barkham, & Proudfoot, 2006; Hickie et al., 2010). The current study, along with a recent study by Kivi et al (2014) extends this research, adding to the evidence supporting the effect of ICBT among primary care patients.

Table 2

Within group and between group effect sizes for measures of depression in studies of Internet-based or computerized CBT

	Intervention groups	Population	N	Post-treatment		Follow-up
				Within-group ES	Between-group ES	Within-group ES
Høifødt, Lillevoll et al., 2014 (paper II)	MoodGYM + short f2f vs delayed treatment control for 7 weeks	Adults recruited from primary care with depressive symptoms (BDI-II ≥ 10)	106	ICBT: $d = -0.98^{\dagger}$ Control: $d = -0.65$	$d = 0.65$	$d = -0.81$
Farrer et al., 2011	MoodGYM + telephone tracking vs MoodGYM only vs control for 6 weeks	Callers to a national helpline with psychological distress (K10 ≥ 22)	155	n/a	$g = 0.76^d$ $g = 1.04^e$	n/a
Christensen et al., 2004	MoodGYM + telephone tracking vs control for 6 weeks	Adults with psychological distress (K10 ≥ 20) – subgroup CES-D ≥ 16	369	n/a	$d = 0.90$	n/a
Hickie et al., 2010	MoodGYM + enhanced GP care vs enhanced GP care for 8 weeks	Primary care patients with psychological distress (K10 ≥ 20)	56	n/a	$d = 0.40^a$	n/a
Cavanagh et al., 2006	Beating the Blues in routine care clinics, naturalistic study	Routine care patients with poor psychological well-being (GHQ-12 ≥ 4)	219	ES = 0.56 ^c	n/a	n/a
Hedman et al., 2014	ICBT + e-mail therapist support in a clinic offering ICBT as routine care	Routine care patients with depression (MINI)	1203	$d = 1.27^f$	n/a	$d = 1.28^f$
Kivi et al., 2014	Depressionshjälpen [®] with therapist guidance vs TAU for 12 weeks	Primary care patients with diagnosis of mild to moderate depression (MINI + MADRS < 35)	90	ICBT: $d = 1.09^b$ TAU: $d = 1.27^b$	$d = .00^b$	n/a
Ruwaard et al., 2009	ICBT + e-mail therapist support vs WLC for 11 weeks	Adults with depressive symptoms (BDI between 10-29)	54	n/a	$d = 0.70^b$	n/a
Perini et al., 2009	Sadness program + e-mail therapist support vs WLC for 8 weeks	Adults with depressive symptoms in an online clinic (PHQ > 5)	45	ICBT: $d = 1.15$ Control: $d = 0.50$	$d = 0.63^b$	n/a
Wagner et al., 2013	ICBT + e-mail therapist support vs f2f CBT for 8 weeks	Adults with depressive symptoms (BDI ≥ 12)	62	ICBT: $d = 1.27^b$ f2f: $d = 1.37^b$	$d = .00^b$	$d = 2.00$ $d = 1.04$
Johansson et al., 2012	Tailored ICBT + e-mail therapist support vs Standard ICBT + therapist support for 10 weeks	Adults with depressive symptoms (MADRS between 14-36)	121	TA: $d = 1.48^b$ ST: $d = 0.98^b$	$d = 0.84^b$ $d = 0.57^b$	$d = 1.55^b$ $d = 1.01^b$

[†]Negative value indicates decrease in BDI-II scores at posttest.

^ameasured by SPHERE-12. In favor of MoodGYM + enhanced care. ^bmeasured by BDI-II. ^cUncontrolled pre-post effect size, measured by self-report in CBT program.

^dMoodGYM only vs control, in favor of MoodGYM. Measured by CES-D. ^eMoodGYM + telephone tracking vs control, in favor of MoodGYM. Measured by CES-D. Measured by MADRS.

ES = Effect size; F2f = face-to-face consultations with a therapist; BDI-II = Beck Depression Inventory II; GP = general practitioner; TAU = treatment as usual; K10 = Kessler Psychological Distress Scale; SPHERE-12 = Somatic and Psychological Health Report; MINI = Mini International Neuropsychiatric Interview; MADRS = Montgomery Åsberg Depression Rating Scale; CES-D = Centre for Epidemiological Studies Depression Scale. WLC = wait list control

Within a stepped care model for depression treatment, clinically significant changes in depression scores may indicate the rates of stepping up or stepping down treatment. Patients that are recovered or significantly improved may be eligible to maintenance treatment, or have no further treatment needs. Patients that experience no change or even deteriorate should receive high intensity treatment, in the Norwegian primary care this would imply referral to specialist care and/or pharmacological treatment. In the full sample, 48.1 % of patients in the treatment group did improve or recover, compared to 18.6 % in the control group.

Research on ICBT to date has encouraged immense optimism, but some recent reviews are reminders that one should not cheer too early. Arnberg and colleagues (2014) point to the fact that few comparisons of ICBT to established treatments are conducted, and they conclude that the evidence so far is insufficient to support widespread implementation. So and colleagues (2013) draw a similar conclusion, arguing that their meta-analytic review were unable to find long-term effects and improved functioning in ICBT patients. Further research need to respond to this critique, and assess treatment effects in a long term perspective and by means of other measures.

The role of support in guided self-help

An issue debated in the literature is the necessary and sufficient degree of support in guided ICBT. In terms of support, the intervention in study II falls into the category of ICBT with a moderate to high degree of support, based on the amount, frequency and type (Barak et al., 2009; Titov, 2011). The purpose of the sessions with the therapist was to monitor symptom development through the course of treatment and support the participant in the use of MoodGYM and application of skills and techniques. The participants were supported through discussions of general principles presented in the program and motivation to sustained use of MoodGYM in a fashion that therapists without particular training in CBT could provide. It is possible that the amount of support exceeds the optimal amount, and that

similar outcomes are achievable with less therapist time. Indeed, studies with 10-15 minutes therapist time per participants have yielded strong effects e.g. (Farrer et al., 2011; Kivi et al., 2014). The most common support type provided in ICBT is e-mail or similar asynchronous communication. There are few direct comparisons of different support modalities (e.g. face-to-face vs. e-mail), although some evidence suggest equal benefits (Pier, Austin, Klein, Mitchell, Schattner, Ciechomski et al., 2008). In addition to amount and type of support, the content of the support varies across interventions. Some aim to support sustained usage of the Internet program by acting as reminders, offer practical/technical help, providing generic feedback and reinforcing participant engagement with the program. On the other hand, some interventions provide therapist contact as an additional therapeutic element that offer more individualized feedback or engage in topics raised by the participants. The design of the current study with only one intervention group does not allow for investigation of the relative contribution of the different intervention elements. The treatment satisfaction reported by participants were overall positive to the treatment as a whole, but indicate that the perceived benefit of the Internet program was less than the benefit from the sessions. In other words, the participants perceived the Internet program as beneficial, but the sessions with the therapist as more beneficial. The interviews in study III sheds light on the participants' experiences with the treatment.

4.3 Participants' experiences of helpfulness

Study III raised the question "What does the patients find helpful in alleviating the depressive symptoms?" The findings from the interviews pointed to different meanings attributed to the treatment elements and the involvement of the participants. The Internet program provided information relevant to their situation that involved recognition ("this has to do with me") and an extension of their current knowledge (psychoeducation). The participants' own efforts in addressing the problem by seeking help, engaging with the

Internet program and practicing skills in everyday life gave a sense of relief and helped to break the negative cycles of depression. The consultations with the therapists emerge as important, both as a conversation partner to share thoughts and experiences, and in terms of working with Internet program material. The treatment protocol refrained therapists from delivering CBT separately from MoodGYM, but the discussions of CBT principles during consultations were enhancing the participants' understanding and application of the MoodGYM content.

In relation to the discussion in the field of ICBT research regarding the type, amount and content of support the study shed light on what contributes positively from the perspective of the participant. A recent review by Baumeister et al. (2014) supports the findings by several previous reviews, that guided Internet-based interventions outperform self-directed or unguided interventions. Although the difference found by Baumeister and colleagues was smaller than previous estimates, guided ICBT yields better outcomes relative to unsupported ICBT. The mechanisms for this difference in effect are poorly understood, but one suggested explanation is that guidance reinforces adherence to the Internet program, that again affects outcome. Findings also suggest that support need not be provided by a clinician, but may be provided by students, technicians or coaches (Baumeister et al., 2014). A study by Mohr et al (2013) compared ICBT with and without telecouching, - a manualized telephone intervention aimed at improving adherence. The telecouch intervention was successful in improving adherence, but intriguingly, the change in depression severity scores across groups did not correspond to the difference in adherence. In fact, both groups displayed a significant decline in depression compared to the control group. Similar findings appeared in other studies by Farrer et al (2011) and Berger et al (2011). There are some common features of these studies in the content of the support provided. The support addressed issues with program usage, reinforcing the participants' work, but did not engage in discussions regarding

CBT content. The findings of study III of this thesis indicate that the discussions with the therapist facilitated the understanding and practice of skills and knowledge from the Internet program, by helping to bridge the gap between theoretical concepts and participants' everyday living. This kind of support differs from other kind of support merely aimed at keeping users "in the program". As of today, research can provide us with few answers regarding the content of support, as this topic has received little attention. The underlying mechanisms resulting in therapeutic change in ICBT require further investigation to be understood, and theories of psychotherapeutic change in general may offer a framework. In closing the discussion of the studies in this thesis, some limitations of study III will be considered, before a learning framework is applied to organize the findings.

Limitations of the interview study

The phenomenological approach provides insights into the participants internal work as they go along with the treatment, and what dimensions are perceived as meaningful in this work. The results tell us about the interaction with the therapist, the meaning of MoodGYM, and the engagement of the patient, - dimensions that can be organized within the perspective of different kinds of learning as attempted in the previous section. This perspective can be valuable for therapists engaging in guided self help in their practice, by encouraging reflection on the individual needs of patients undergoing treatment and how to support the patient in their work towards recovery. It is, of course, important to point out that there will be needs specific of each individual situation that must be taken into consideration, and that the aim of this research is to discover the commonalities across individual experiences.

Setting out to uncover the invariables across subjective experiences of the given treatment, semi structured individual interviews were conducted. The interviews capture well the conscious perceptions and experiences of the participants. This is, after all, the material of interest in studies taking on a phenomenological stance, - the life world of the person.

However, it presumes that participants are able to verbalize and express these experiences at the time of the interview. Subtle processes that may be of importance can be difficult to convey at this one occasion. Timing of the interview could also influence what the participant remember or consider important. Perceptions expressed immediately after treatment completion can differ from later opinions, when the treatment is at a distance.

Also, the social context of interviews and the unequal relationship between interviewer and participant are likely to influence the study. Few participants directly expressed negative views of MoodGYM, the therapists or the treatment model as a whole, hence, one cannot rule out the effect of social desirability. Potential participants may have abstained from consenting to interviews to avoid expressing negative experiences, or the respondent may have refrained from expressing views they perceive as undesirable. Indeed, several participants interviewed did not experience the treatment as sufficient for their needs, as is also evident from table 1 in the previous method section showing several individuals with no symptom change. As reported in paper III, some participants came to realize that they desired a regular face-to-face treatment because the sessions with the therapist were most meaningful to them. Others did not experience the material of MoodGYM as suited for their needs, and hence, they did not acquire relevant knowledge, whereas others found it difficult to make use of the knowledge. Although there were few participants directly expressing negative views, they actually did report difficulties that were along the dimensions presented in the results.

ICBT in a learning perspective

The efficacy of psychotherapy has been well established since Eysenck's 1952 critical review that dismissed any therapeutic efficacy and even suggested deleterious effects (Lambert, Bergin, & Garfield, 2004). Numerous studies and reviews support the superior effect of psychotherapy to no-treatment or placebo, but the mechanisms by which the effect is produced is not fully understood. It is, more or less, commonly accepted that multiple factors

contribute to therapeutic change, as implied by the contextual model (Scaturo, 2010; Wampold, 2015). Psychotherapy is not merely the application of “techniques” or “method” to cure a disorder, but factors relating to the therapist, individual patient and relationship between them are critical contributors to outcome. Another conceptualization of psychotherapy through a learning perspective (e.g. Scaturo, 2010) may be of use in understanding different processes at work, and perhaps is well suited to the research on ICBT. A learning framework also seems natural due to the strong emphasis on patient psychoeducation and learning of self-therapeutic skills in ICBT.

Building on educational psychology, Scaturo (2010) argue for a tripartite learning conceptualization of psychotherapy, in which three progressive phases are outlined, incorporating three types of learning, labelled emotional, cognitive and behavioral learning. Firstly, tacit emotional learning happens within the alliance building phase, within the facilitative conditions of the therapeutic alliance and the security of the treatment context. Secondly, cognitive or instrumental learning involves acquiring new declarative knowledge and skills that are comprised by for instance, specific CBT techniques. Thirdly, a behavioral process is outlined in which the individual operates in his/her natural environment, rehearsing knowledge and skills from therapy, gradually increasing adaptive functioning. The findings of study III and the contribution of the various treatment elements (the Internet program, the relationship with the therapist and the patient himself) can be viewed in light of such a conceptualization, as organized in table 3.

Table 3 *Organization of themes emerging in study III in a learning framework.*

<i>Treatment element</i>	<i>Emotional learning</i>	<i>Cognitive learning</i>	<i>Behavioral learning</i>
<i>MoodGYM</i>		Providing new knowledge	
<i>Participant</i>	Addressing the problem	Restructuring new knowledge	Changing interactions and perceptions in everyday life
<i>Relationship/dialogue with therapist</i>	Sharing thoughts and feelings.	Supporting the use of MoodGYM	
	Receiving feedback and advice		

Emotional learning

Participants emphasized the mere act of help-seeking and initiating treatment as giving a sense of relief and positive affect. They were fulfilling a need to move forward and had positive expectations and hope for change. This readiness for change is described in the stages of change theory (e.g. Prochaska & Norcross, 2001) as a preparation that includes intention and action, and is reflecting an emotional readiness within the participant. The emotional learning also includes the trusting relationship and dialogue with the therapist as a vital part of treatment that in itself cultivated the healing process. The basis of the trusting relationship is the therapeutic setting building on principles of professional ethics and integrity and the emotional security influenced by the therapeutic alliance (Scaturo, 2010). This enabled participants to express their thoughts and feelings without fear of judgement and to receive confirmation and support.

Cognitive learning

Cognitive learning concerns the acquisition of declarative knowledge, in this study, elements of cognitive theory of depression (e.g. the depressive triad and negative automatic thoughts) and principles of CBT for depression (e.g. cognitive restructuring and behavioral activation). In the participants accounts, cognitive learning is reflected where participants report gaining

new insights and knowledge from MoodGYM, even if not all of the program content were of use to them. The participants themselves showed an ability, at times impressively creative, to interact with the material, adapting it to the best of their use. The dialogue with the therapist also facilitated this adaptation that helped to enhance the understanding of the theoretical concepts presented in the program.

Behavioral learning

Knowledge acquired from the Internet program was integrated into everyday life through the practice of skills (e.g. reality checking negative assumptions) and behavioral changes. This corresponds to the behavioral learning process (Scaturo, 2010), that again served to break negative cycles and increase mastery and empowerment.

Avenues for future research

It can be argued that the learning experiences in psychotherapy can be initiated by interaction with a computer program as well as a psychotherapist (Miclea, Miclea, & Ciuca, 2008), and that the therapist and the computer program contributes to the patients' work towards recovery through complementary processes. The different types of Internet-based or computerized treatments (guided vs self-directed; e-mail vs face-to-face vs telephone guidance) may facilitate the forms of learning in different ways. Treatment packages differ in their presentation of program content (some rely heavily on text presentations, others provide videos and animations) and support content (therapeutic vs non-therapeutic), and this may influence learning experiences and thereby outcome. Interesting questions arise from such a perspective. How can Internet-based interventions best stimulate emotional, cognitive and behavioral learning in users? Can emotional learning occur only in the presence of a therapist, or can it be stimulated from interaction with technology? Some research suggest a relationship can be formed to unguided computerized programs (Purves et al., 2013), and the therapeutic alliance in guided interventions is not well understood. Further, patients may have different

needs regarding emotional support and other forms of learning, and hence, different needs of support in Internet-based treatments.

Which elements of ICBT are necessary and sufficient to achieve therapeutic change is an area of future study. A learning perspective on self-help treatments may aid in understanding which processes are supported by the self-help program and therapist (if present), and the role of the patient during the course of treatment.

Conclusion

The studies point to some challenges and possibilities of Internet-based CBT for depression. As a means for a universal prevention of depression in high-school, the evidence does not support effectiveness of the MoodGYM intervention. However, the study is hampered by power issues, - it might not be able to detect relevant changes, due to the very low number of adherent participants. This, in it self, points to a notable challenge for particularly unguided interventions, namely poor adherence. With adherence problems in mind, and the inconsistent findings in previous research regarding universal depression prevention using CBT, the value of large scale dissemination is questionable. Using ICBT for high-risk subgroups with guidance given by school nurses or counsellors seems a more fruitful way to go, and is more in line with the rational of CBT aiming to alter the negative thinking of depressed individuals.

As an initial treatment choice for depressed primary care patients, guided ICBT with MoodGYM bears some promise. There was a significant reduction in symptoms of depression and anxiety and an increase in life satisfaction in the intervention group compared to the control group. These findings are in line with other studies of ICBT for depression. The participants' accounts of what caused positive changes elucidated the dynamic involving the active engagement of the participant, the relevant content of MoodGYM and the sessions with the therapist.

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Paper I

RESEARCH ARTICLE

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Uptake and adherence of a self-directed internet-based mental health intervention with tailored e-mail reminders in senior high schools in Norway

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Abstract

Background: Internet-based cognitive behavioural therapy (ICBT) is a promising approach to the prevention and reduction of depressive symptoms among adolescents. This study aimed to evaluate the feasibility and efficacy of disseminating a self-directed internet-based mental health intervention (MoodGYM) in senior high schools. It also sought to investigate possible effects of tailored and weekly e-mail reminders on initial uptake and adherence to the intervention.

Method: A baseline survey was conducted in four senior high schools in two Norwegian municipalities (n = 1337). 52.8% (707/1337) of the students consented to further participation in the trial and were randomly allocated to one of three MoodGYM intervention groups (tailored weekly e-mail reminder (n = 175), standardized weekly e-mail reminder (n = 176) or no e-mail reminder (n = 175)) or a waitlist control group (n = 180). We tested for effects of the intervention on depression and self-esteem using multivariate analysis of variance, effects of tailored e-mail and self-reported current need of help on initial uptake of the intervention using logistic regression and the effect of weekly e-mails on adherence using ordinal regression.

Results: There was substantial non-participation from the intervention, with only 8.5% (45/527) participants logging on to MoodGYM, and few proceeding beyond the first part of the programme. No significant effect on depression or self-esteem was found among the sample as a whole or among participants with elevated depression scores at baseline. Having a higher average grade in senior high school predicted initial uptake of the intervention, but tailored e-mail and self-reported current need of help did not. Weekly e-mail prompts did not predict adherence. The main reasons for non-use reported were lack of time/forgetting about it and doubt about the usefulness of the program.

Conclusion: Overall, disseminating a self-directed internet-based intervention to a school population proved difficult despite steps taken to reduce barriers in terms of tailoring feedback and dispatching weekly e-mail reminders. Providing mental health interventions within the school environment is likely to ensure better uptake among senior high school students, but there is a need to effectively communicate that such programmes can be helpful.

Trial registration: The trial was registered retrospectively as ACTRN12612001106820.

Keywords: Internet-based cognitive behavioural therapy, Depression, Adolescents, E-mail support

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Background

Depression among adolescents has been recognized as a significant mental health problem, with point prevalence estimates varying between 1% and 6% [1,2]. Longitudinal studies of community samples estimate a lifetime prevalence of clinical depression up to late adolescence and early adulthood between 4% and 25%. The recurrent nature of depression points to the importance of prevention and early intervention among this group [3].

The majority of adolescents suffering from depression remain untreated [4-6]. Several barriers to help-seeking for common mental health problems have been identified [7-9]. The most prominent include stigma and embarrassment about seeking help, confidentiality concerns and poor mental health literacy and the belief that one should handle problems without outside help (self-reliance).

Using the Internet to offer mental health interventions to the population is a promising approach to overcoming many of these barriers to help-seeking among adolescents, such as stigma, confidentiality concerns and self-reliance. The positive effect of internet-based cognitive behavioural therapy (ICBT) on depression among adults has been documented in randomized controlled trials [10-14] and community populations [15,16]. Although ICBT with therapist support shows larger effect sizes, fully automated, unguided interventions are effective in reducing depressive symptoms [17]. Furthermore, programs aiming to enhance skills on the individual level, such as promoting healthy cognitive and behavioural patterns, may be one means of preventing depression also in currently non-depressed persons [16,18]. The evidence for effectiveness of computerized or internet-based CBT for adolescents and young adults is emerging, with a number of studies reporting that such interventions are effective in preventing or reducing depressive symptoms in adolescents and young adults [19-22] and in schools in particular [23-25]. For example, there is evidence from an Australian study that iCBT can prevent new cases of depression in boys and anxiety in both boys and girls when delivered to students without symptoms in the classroom [cite Calear et al.] This raises the question of whether fully automated ICBT outside the classroom might also be effective as a universal intervention to adolescents in schools, as a mental health promotion tool for the general adolescent population and prevention or early intervention for persons with elevated levels of depressive symptoms.

One factor that may prevent the uptake of fully automated ICBT in individuals with elevated symptoms is poor mental health literacy; for example, having difficulties identifying symptoms of depression. It has been proposed that providing feedback about an individual's level of depression and anxiety might facilitate engagement with e-health applications [26]. Increasing the awareness of symptom level among individuals at risk of depression

could be an effective way of promoting uptake of ICBT for depression. This could be achieved through tailoring feedback based on targeted individual factors. The latter might not only include symptom level but also other factors associated with help-seeking behaviours [9]. Tailoring interventions or feedback are already utilized in life style or health related interventions [27-29] and are emerging within the field of depression [30]. An initial screening including a measure of depression could form the basis for such feedback and thus encourage uptake of the ICBT among adolescents with elevated symptom levels. Adolescents with no depressive symptoms or mental health complaints may have poor motivation to enrol in a mental health promotion program, but a positive framing of the intervention and focus on strengthening protective factors could enhance interest. The cognitive vulnerability model of depression proposes that low self-esteem increases risk of depression, and has received empirical support [31,32]. Thus, this is a relevant factor to address in mental health promotion programs.

An issue considered as a barrier to the implementation of Internet interventions in general, is the poor adherence associated with open access websites compared to monitored settings such as randomized controlled trials [33,34]. The use of "push" factors or reminders has been recommended by several researchers [20,35-37]. Research has yielded encouraging results concerning the effect of reminders (post card, e-mail, telephone or instant messaging prompts) on adherence. Overall, findings suggest that adding reminders encourages sustained usage of intervention web sites [38-42]. However, the results are not unambiguous [43,44]. Further, to our knowledge, the possible benefit of tailored e-mail reminders supporting a self-directed mental health intervention in an adolescent sample has yet to be investigated.

Hypothesis

The overall purpose of the study was to explore the feasibility of disseminating a fully automated, self-directed internet-based mental health intervention (MoodGYM) in high schools. We aimed to test the efficacy of the intervention in reducing depressive symptoms and increasing self-esteem in the sample as a whole, and more specifically in participants with elevated levels of symptoms of depression. We hypothesized that there would be:

1. Reduction of depressive symptoms and increase in self-esteem in the sample as a whole (prevention hypothesis).
2. Reduction of depressive symptoms in participants with elevated scores at baseline (treatment hypothesis).

Furthermore, we aimed to investigate whether e-mail tailoring in terms of providing participants with

relevant feedback, would enhance initial uptake of MoodGYM among students reporting a need for help with psychosocial problems. Further, we aimed to investigate the relationship between weekly reminders and adherence to MoodGYM.

We hypothesized that there would be:

3. Better initial uptake (more participants commencing MoodGYM) among students with a reported current need of help in the tailored e-mail group compared to the group not receiving tailored e-mails.
4. Better adherence (participants persisting in MoodGYM use for a longer period) in the groups receiving weekly reminders.

Method

Design

The study involved a four-arm randomized controlled trial with measures administered at baseline and at post-intervention at 6–7 weeks following the commencement of the intervention. Participants were recruited from four different senior high schools in Troms county in Northern Norway. The schools were not selected at random; rather, the school administration volunteered for participation in the MoodGYM trial. All schools in the county were offered the opportunity to enter the study, but several schools were already participating in alternative interventions or declined for other reasons.

The study was conducted from September to November 2009. It was approved by the Norwegian Regional Ethics Committee North (REK NORD 114–2006). According to Norwegian legislations, individuals between the ages of 16 and 18 years can decide without their parents' consent whether to enter non-intrusive research projects (Norwegian Health Research Act of 2008 [45]). Individuals under the age of 16 need parental consent, but if the adolescent does not wish to disclose information to parents, the legislation indicates that this should be respected. A proportion of students had not yet reached the age of 16 when entering senior high school, but was scheduled to do so within the school term. Since treating students under the age of 16 differently by requesting parental consent might have represented an obstacle to the adolescents, no parental consent was requested. Parents did however receive information about the study from the schools. The Regional Ethics Committee approved the use of the data from participants under the age of 16.

The internet-based intervention

The intervention in the trial was MoodGYM, a cognitive behavioural therapy based interactive program consisting of five modules and a personal workbook [46]. It is

designed to prevent and reduce depressive symptoms in young people. Each module has a specific theme and is designed to take between 30–45 minutes to complete. The first module introduces “characters” that model thinking patterns recognizable to the user. It further demonstrates the interaction between mood and the way of thinking using animated diagrams and interactive exercises. Module two describes different types of dysfunctional thinking and how to challenge the validity of negative thoughts. It also provides a self-assessment for dysfunctional thought. Module three presents the user with several strategies for overcoming dysfunctional thoughts and also assesses self-esteem to provide training to increase it. The next module, number four, looks at life-event stress, pleasant events and activities in order to increase focus upon the activities creating more positive experiences and emotions. The final and fifth module covers problems concerning typical issues regarding relationship break-ups. Exercises from the workbook are integrated into each of the above modules. Every module is designed to be completed in approximately 45–60 minutes, and in the latest version of the MoodGYM program (Mark III) core assessments are compulsory not allowing the user to skip or alternate between the different modules.

Participant recruitment

Participants were recruited through visits of the research group to the four participating schools. The recruitment process included the delivery of a short lecture about mental health in general, and a presentation on MoodGYM in particular, followed by an invitation to the students to participate in a study of MoodGYM. Each participant in the study signed a written consent form at the day of the information session and received a unique identification number to be entered in the baseline and post intervention questionnaire. Students consenting to enter the study could either, depending on their preference, choose to participate in the baseline survey only, or in the MoodGYM trial, as well. As an incentive to participate, the id-number of all students completing the baseline survey was entered into a lottery with a chance to win an iPod. For those consenting to participate in the MoodGYM trial, a second lottery with an iPod prize was arranged.

Measures

Participant characteristics

Demographic characteristics including gender, age and average grade in high school were collected as were self-reported current and previous need of help for psychological problems and use of mental health services.

Depressive symptoms

Level of depression was measured using a Norwegian version of the Centre for Epidemiologic Studies Depression

scale (CES-D) designed to measure depressive symptomatology in the general population [47]. Responses are rated on a four-point scale. Scores range from 0 to 60, where scores 16 or higher are regarded as reflecting a clinical level of depression. However, due to developmental factors in adolescent samples the CES-D score may be inflated [48]. A cut-off score above 24 has therefore been suggested to detect clinically diagnosable cases [49]. The Norwegian version of this scale has previously been used in studies with satisfactory internal consistency [50-52]. The Cronbach alpha for the current study was .88. The tailored e-mails differentiated between low risk of depression (CES-D sum score < 16), moderate risk (16-24) and high risk (> 24).

Self-efficacy

Self-efficacy was assessed using the Norwegian version of the General Self-Efficacy Scale (GSE) [53]. The scale consists of 10 items and is designed to assess the individual's belief in their ability to handle difficult situations in an appropriate way. Responses are reported on a four-point scale ranging from "not at all true" to "exactly true". The psychometric properties of the Norwegian version of this scale has been found satisfactory [54]. The Cronbach alpha for the current study was .88. Individually tailored e-mails in this study differentiated between individuals with low (sum score < 30) and high (30 or more) self-efficacy.

Self-esteem

Self-esteem was assessed using the Norwegian version of the Rosenberg Self Esteem Scale (RSES) [55] as a measure of global self-esteem. The scale consists of 10 statements related to overall feelings of self-worth or self-acceptance. The items are answered on a four-point scale ranging from strongly agree (1) to strongly disagree (4) yielding a score between 10 and 40. The Norwegian version of the scale has yielded satisfactory psychometric properties [56]. The Cronbach alpha obtained in the current study was .88. Individually tailored e-mails in this study differentiated between individuals with low (sum score < 25) and high (25 or more) self-esteem.

Reasons for non-use

The post-intervention questionnaire included questions regarding reasons for non-use of the intervention.

Intervention study procedure

The baseline survey was undertaken on the day of the information session at the school. Participants either completed the survey online (56.7%), or on paper (43.3%). Participants who consented to participate in the trial were randomly allocated to either a control group or one of three intervention groups with or without reminders. The randomization was undertaken using the SPSS to generate

random numbers, which then were ordered in ascending order and allocated numbers from 1-4. This was undertaken by the first author. Participants allocated to the MoodGYM trial intervention groups received an e-mail within one week of completing the baseline survey at their school, containing their user name and password for the internet program.

The intervention was undertaken during the participant's own time. Except for the use of the automated e-mails in two conditions, the ICBT-program delivery was unguided. Progress through MoodGYM was tracked on and later retrieved from a server at the Australian National University (ANU). Six weeks after the pre-test the researchers returned to the school to collect the post-intervention data.

Following completion of the post-intervention phase, the researchers debriefed the students about the study design and explained to participants in the control group how sign up to undertake the MoodGYM program.

Intervention groups in the MoodGYM trial

Participants were allocated into either a control group (group 1; n = 180) or one of the three intervention groups: no reminders (group 2; n = 176), standard e-mail reminders (group 3; n = 176) or tailored e-mail reminders (group 4; n = 175).

The content of each of the interventions was as follows:

Group 1. The control group received an e-mail within one week after the baseline survey informing them that they were enrolled in the study and would receive further information. After the post-test all students were informed that they had been part of the control group, and about how to obtain access to MoodGYM.

Group 2. MoodGYM without reminders. This group received an e-mail within one week after the baseline survey with user name and password to register in MoodGYM. They were instructed to complete one module of MoodGYM per week.

Group 3. MoodGYM with standard reminders. The same content as Group 2 and standard e-mails preceding each module providing a general introduction to the topic of each module.

Group 4. MoodGYM with tailored reminders. The same content as Group 2 and individually tailored e-mails preceding each module. The tailored information was based on data collected in the baseline survey on risk of depression, level of self-efficacy and self-esteem. These variables were selected based on their interrelatedness and relevance to help-seeking behaviors [57-59]. The first tailored message included the standard general introduction to module one, as well as feedback on the individual risk of depression based on the CES-D; the second message included the standard general introduction to module two as well as information about their current level of self-

esteem; the third message provided information concerning the content of module three in MoodGYM adapted to their level of depression; the fourth message provided feedback regarding their level of self-efficacy which was related to the content of module four; the fifth message introduced the topic of module five adapted to their level of self-esteem. The e-mails to participants with low levels of depressive symptoms, high self-esteem and self-efficacy were tailored to encourage use of MoodGYM in order to learn more about mental health problems.

The e-mails were automatically generated by software separate from the MoodGYM program, with all participants in groups 3 and 4 receiving weekly e-mails regardless of their level of MoodGYM use. The first author undertook the process of registering participants in the e-mail software and ensuring the weekly e-mail dispatch.

Statistical analysis

Data analyses were performed using IBM SPSS statistics 19 for Windows. We allowed for 10% missing values on the CES-D, RSES and GSE scales, replacing them with mean values.

Chi square tests and one-way analyses of variance (ANOVA) were conducted to assess whether the MoodGYM trial participants differed in demographic characteristics and depressive symptoms, self-esteem and self-efficacy from the larger sample of students who participated in the baseline survey only. Intra-class correlations for each year (year 1, 2 and 3) within each school were calculated to assess dependence in the data.

To test hypothesis one, whether there was a reduction in depressive symptoms and an increase in self-esteem in the sample as a whole, a multivariate analysis of variance was conducted. The independent variable was MoodGYM use (yes/no).

To test hypothesis two, whether there was a reduction of depressive symptoms in participants with elevated scores (CES-D > 16) we conducted a multivariate analysis of variance. We also tested if there was an increase in self-esteem in this group. The independent variable was MoodGYM use (yes/no).

To test hypothesis three, whether a self-reported current need of help and tailored e-mail reminders predict uptake, a logistic regression analysis was performed using the independent variables current need of help, intervention group and the interaction variable with current need and group. Uptake was defined as use or non-use of MoodGYM.

To test hypothesis four, whether weekly e-mail reminders increase adherence, an ordinal regression analysis was conducted with weekly reminders as the independent variable. Adherence was measured as number of modules with 25% progression or more, with modules 2–5 collapsed to one category to increase power. Accordingly, adherence was divided into categories of non-participation, one module or two or more modules.

Previous studies of internet-based self-help for depression and anxiety have shown effect-sizes ranging from 0.00 to 0.90 both for depression and anxiety measures. Effect-size of 0.6 at post-test was estimated. To test for intergroup differences of this magnitude by analysis of variance at a 0.05 level and with a power of 0.80, a sample of 45 in each condition is needed. To allow for an average attrition rate of 50%, 360 participants need to be recruited.

Results

A total of 1337 students aged between 15 and 20 years from four senior high schools completed the baseline survey of whom 775 students consented to participate in the MoodGYM trial. Table 1 shows gender distribution, mean age, depression, self-efficacy and self-esteem scores and percentage of participants reporting a current need for help in the baseline survey-only group and in the MoodGYM trial group, respectively. Although 775 students consented to participate in the MoodGYM trial, only 707 were enrolled in the trial due to a data entry error.

MoodGYM trial versus survey-only participants

Multivariate analysis of variance and chi square tests were performed to assess differences between the MoodGYM group and the baseline survey-only group in gender, age, average grade, depressive symptoms, self-efficacy,

Table 1 Sample characteristics and assessment of differences between the survey group and the MoodGYM trial group

	Baseline survey only n = 562				MoodGYM trial n = 775				p-value
	n	%	mean	sd	n	%	mean	sd	
Female gender	235	41.8			440	56.8			<.001
Age			16.78	1.04			16.80	1.00	.63
Average grade			3.95	0.78			4.13	0.80	<.001
Depressive symptoms			9.81	5.07			11.18	5.96	<.001
Self-efficacy			29.32	5.01			29.28	4.61	.88
Self-esteem			18.92	3.96			17.99	4.21	<.001
Current need of help	51	9.07			130	16.77			<.001

self-esteem and self-reported current need of help. The MoodGYM trial group reported a higher average grade $F(1,1285) = 13.90, p < .001$, more depressive symptoms $F(1,1332) = 19.23, p < .001$, and lower self-esteem $F(1,1317) = 16.31, p < .001$ compared to the survey-only group. There was no significant difference in age and self-efficacy scores. Also, in the MoodGYM trial group there were more females, Pearson's $\chi^2(1) = 29.16, p < .001$, and more individuals self-reporting current need of help Pearson's $\chi^2(1) = 16.50, p < .001$.

Testing of assumptions in MoodGYM trial

To test the assumption of statistically independent observations, intra-class correlations (ICCs) were calculated for each of the outcome measures within the first, second and third year at each school. There was no evidence of clusters based on year. Intra-class correlations were 0.03 for depression (CES-D), 0.05 for self-esteem, 0.02 for initial MoodGYM uptake and 0.01 for MoodGYM adherence, supporting the notion of independent observations.

Attrition

Figure 1 presents the flow of participants through the trial. 8.54% (45/527) of the participants in the intervention groups actually signed on and used MoodGYM. 70.02% (369/527) of participants randomized into an intervention group returned post intervention questionnaires. Of these, 40.23% (212/527) reported post- intervention data regarding non-use.

Intervention efficacy

Due to the low uptake of the intervention, the users of MoodGYM were collapsed into one group regardless of their initial allocation for the purpose of examining intervention effects. A multivariate analysis of variance was performed, comparing MoodGYM users with complete pre- and post intervention data ($n = 42$) to non-users ($n = 483$). Using Pillai's trace testing for differences between the groups on depression or self-esteem, no significant differences was found, $F(2,522) = 1.04, p = .36$.

To test for possible intervention effects among participants with elevated symptoms the analysis was repeated

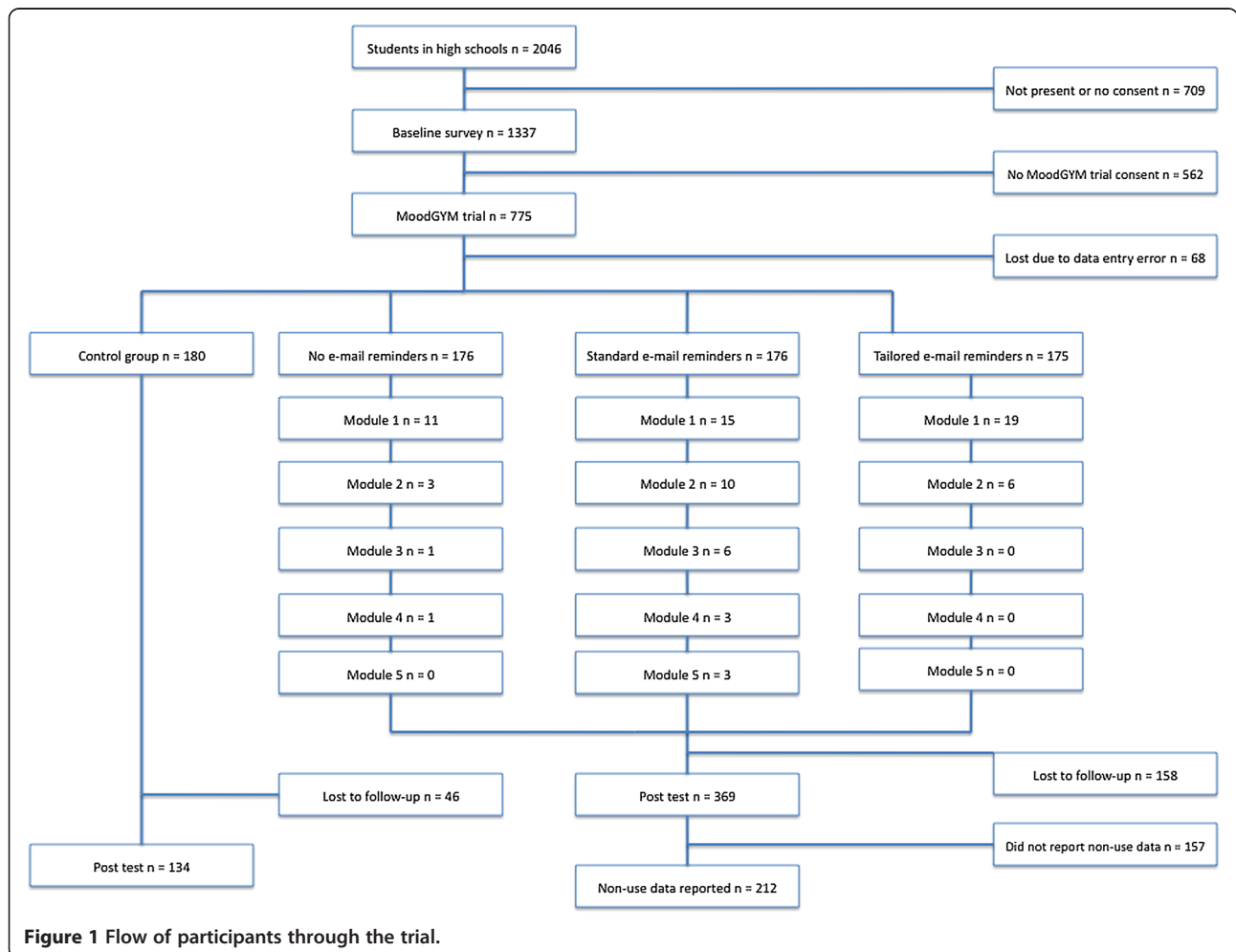


Figure 1 Flow of participants through the trial.

for participants with a CES-D score above the 16-point cutoff at baseline. Using Pillai's trace testing for differences between the MoodGYM users (n = 19) and non-users (n = 179) with complete pre- and post data, no significant differences were found for depression and self-esteem, $F(2,195) = 0.01, p = .99$.

Univariate correlations

As the hypothesized relationships regarding uptake and adherence only concern the intervention groups, the control group will be excluded from further analysis. Table 2 provides an overview of the variable correlations across the MoodGYM trial intervention groups. All variables, except MoodGYM use, are measured at baseline.

Baseline differences between trial groups

We examined possible differences at baseline in depressive symptoms, self-esteem and self-efficacy between the three intervention groups. Using Pillai's trace, there were no significant differences across intervention groups in gender, age, average grade, current need of help, depressive symptoms, self-esteem or self-efficacy $F(14,998), 1.16, p = .30$. The number of participants reporting a current need for help in each intervention group ranged from 24 to 35, $\chi^2(2) = 3.02, p = .21$.

Effects of tailored e-mail reminders and current need of help on initial uptake

A hierarchical logistic regression analysis was performed to test for possible effects of tailored e-mail reminders and self-reported current need of help on initial uptake. The overall uptake of MoodGYM across the three intervention

groups was unexpectedly low, with only 45 participants (8.54%) entering the program. The predictors were entered blockwise as follows: gender, age, average grade; intervention group affiliation and current need of help; and intervention group affiliation by current need of help. The final model was significant, $\chi^2(8) = 20.36, p = .009$. However, the only significant predictor of initial uptake was average grade, (Wald statistic = 12.73, $p < .001$) with an odds ratio of 2.37 (95% CI 1.48-3.80). Intervention group affiliation did not predict initial uptake of MoodGYM, and nor did current need of help or the interaction variable.

Effect of weekly reminders on adherence

An ordinal regression analysis was performed to test for possible effects of weekly e-mail reminders on adherence. A negative log-log link function was selected because lower values of the outcome variable are more likely to occur. Due to the substantial attrition from the intervention, users persisting from module 2 and onwards were collapsed to form one group in the analysis in order to increase power. As such, adherence was measured as 0 modules, 1 module or 2 or more modules. The overall model was non-significant, $\chi^2(1) = 1.92, p = .17$, indicating that the weekly reminders did not predict adherence.

Data regarding reasons for non-usage

Considering the low uptake rate we investigated possible reasons for non-use reported in the group of non-users (n = 662) compared to the MoodGYM users (n = 45). We ran crosstabs testing for between group differences using chi-square tests. As there were no differences in

Table 2 Variable correlations across the MoodGYM intervention groups

	Gender	Age	Average grade	Current need	Depression	Self-esteem	Self-efficacy	MoodGYM use
Gender	-							
Age	-.09*	-						
n	525							
Average grade	.09*	-.14**	-					
n	509	507						
Current need	.11*	.13**	-.13**	-				
n	521	519	503					
Depression	.20***	.06	-.15***	.57***	-			
n	527	525	509	521				
Self-esteem	-.25***	.00	.24***	-.42***	-.65***	-		
n	524	522	506	518	524			
Self-efficacy	-.13**	-.03	.22***	-.25***	-.40***	.51***	-	
n	521	519	504	515	521	518		
MoodGYM use	.03	-.02	.16***	.04	.07	-.08	-.07	-
n	527	525	509	521	527	524	521	

*p < .05. **p < .01. ***p < .001.

Note. Gender: Higher value represents female. Average grade: Range is 1 to 6. Current need and MoodGYM use: Dichotomous yes/no variables.

the reports from users versus non-users, the results are presented for the sample as a whole in Table 3.

Discussion

This study aimed to explore the feasibility of disseminating a fully automated self-directed internet-based mental health intervention in senior high schools, and highlights several problems with this procedure. We also aimed to investigate whether automated, tailored e-mails, compared to standardized e-mails, could enhance uptake of the intervention, particularly among those expressing a need for help. The results did not provide evidence to support this idea. Finally, we aimed to explore whether weekly e-mail reminders increased adherence to MoodGYM, but this was not supported by the data.

We found that students consenting to participate in the MoodGYM trial reported more depressive symptoms than those who opted to complete the baseline survey only. Also, students who consented to participating in the trial were more likely to report a current need of help for psychosocial issues. This suggests that those with depression or other psychosocial issues were more open to the intervention than their counterparts. Females were also more likely to volunteer for the trial group, possibly because young women report higher levels of depressive symptoms than men, a finding in line with the literature on gender differences in depression [60].

This study found no support for the prevention hypothesis, that MoodGYM would enhance the participants' self-esteem and reduce risk of depression. Among participants with elevated baseline scores on depression and low self-esteem scores, there was no significant change in the expected directions, thus the treatment hypothesis did not receive support either. Previous research has provided early support for the effectiveness of MoodGYM in reducing depression [24,61] but effects

have been variable ranging from small in a universal sample of students in schools [24] to large in an adult telecounselling environment [11]. One explanation for the lack of effect in our study might be that the study does not have sufficient power to yield an effect of a smaller magnitude. Furthermore, very few users proceeded beyond the first two modules, suggesting that the participants received an insufficient dose of the intervention to effect changes in depression or self-esteem.

The hypothesis that individually tailored e-mails would promote the uptake of MoodGYM, particularly among students expressing a current need for support, was not supported. Nor did standardized e-mail prompting enhance initial uptake, compared to providing only the starter e-mail. This contradicts other research reporting an effect of the use of e-mail reminders to increase response rates [39-41]. The only significant predictor of initial uptake was average grade in senior high school, with higher grades predicting initial uptake. The relationship between average grade and use of a mental health intervention is unclear, but it is possible that students who are more conscientious in their school work tend to also be more conscientious in following the study protocol once they have consented.

There could be several explanations for why e-mail tailoring did not enhance initial uptake. Firstly, it is possible that the information session and tailored e-mail content was not able to convey the message in a convincing manner. Recent research indicates that online interventions were the preferred mode of delivery of mental health services in only 16% of a sample of Australian adolescents [62]. We did not set out to investigate the preferred service mode in our study, but some 30% of respondents reported that they doubted the usefulness of the intervention. Previous research has shown that beliefs about treatment are significant predictors of perceived need for treatment [63], and also of adherence to an internet-based depression prevention intervention [64]. Internet-based interventions

Table 3 Reasons for non-use

Question	n	Somewhat or fully disagree	Neither disagree nor agree	Somewhat or fully agree
<i>I did not have access to a computer where I could work undisturbed</i>	212	157 74.1%	25 11.8%	30 14.1%
<i>I doubt that such a program can help me</i>	210	59 28.1%	87 41.4%	64 30.5%
<i>I forgot about it or could not spare the time</i>	208	36 17.3%	52 25%	120 57.7%
<i>I did not have the need for or interest in such a program</i>	211	78 36.9%	89 42.2%	44 20.9%
<i>I felt the need to talk to someone, rather than doing this program</i>	211	83 39.3%	67 31.8%	61 28.9%
<i>I did not feel sure that I was anonymous</i>	211	149 70.6%	32 15.2%	30 14.2%

may be disadvantaged by a lack of knowledge among young people of its possible benefits in the general population, and thus be considered less desirable than alternative treatments. Considering the possible reluctance by young people to undertake online interventions, the e-mail content might be important in promoting the use of MoodGYM. The content used in the current trial was formulated by the research group, and we did not undertake a pilot study to explore responses to the wording of the e-mails. Secondly, there is the possibility that the tailored e-mails initiated help-seeking behaviours that did not include MoodGYM, e.g. seeking counseling from the school nurse. It has been reported that frequency of access of an online health promotion web site (YooMagazine) that focused on mental health literacy, early detection of difficulties and help-seeking was associated with greater off-line help-seeking behaviours in an adolescent sample [65]. Off-line help-seeking was not measured in the current study. Thirdly, we cannot rule out errors of measurement as a possible explanation. For instance, we do not know that students actually received and read the e-mails, even if they were dispatched to the correct addresses. There is the possibility that they were considered spam, and perhaps not even appeared in the student's inbox. It is also possible that students did not regularly check their e-mail. Short Messaging Service (SMS) should be considered as a means of delivering prompting messages. Finally, the study was not sufficiently powered to detect a small effect of tailoring e-mails. Only 20 to 30 individuals in each intervention group expressed a need for help, and only 45 individuals used MoodGYM across the three intervention groups. Thus, the ability to detect small to moderate effects was limited.

Lack of power may also have interfered with testing the hypothesis that weekly e-mail prompting (standardized or tailored e-mails) would enhance adherence to MoodGYM. Due to the low number of MoodGYM users, and the substantial attrition during the first and second module, we chose to merge the data of users of two or more modules into one group, comparing it to that for users of one module and non-users. Despite these steps taken to increase power, there was no effect of receiving weekly prompts. There is other evidence that reminder e-mails increase adherence in adult community samples [16], but it is uncertain if this is the case with adolescents, or if more extensive support is necessary for this group. Other school-based studies have provided an online intervention as part of the curriculum, undertaken within the school environment and led by a teacher or professional. This includes a study of the MoodGYM intervention employed in this study [24]. This mode of delivery attracted more users than did the current self-directed intervention completed outside school hours, and retention was superior [24,66,67].

Allowing for internet based interventions to be implemented during school hours deals with the most prominent reason for non-use reported in our data, namely that the students could not spare the time or forgot about the programme. It seems that the self-directed nature of this mode of delivery was not suitable for the sample in this study, and the findings are similar to previous research, where there was substantial drop-out in a community sample of adolescents [37]. In a monitored environment, there is less drop-out [23,37]. When attempting a universal delivery of mental health programmes regardless of individual need or risk, completely self-directed interventions might not be an appropriate procedure to engage adolescents, as their motivation and persistence may fluctuate, as suggested by our results. Rather, a structured approach would seem preferable. There is some evidence of the effectiveness of universal depression prevention programmes [24], and pursuing the most appropriate means of implementing such programmes is warranted [68].

The findings challenge the approach of promoting a self-directed intervention among senior high school students. Possibly, alternative initial strategies of increasing interest, involvement or commitment in students might have increased uptake. However, the current study shows that tailored feedback adapted to the participants' level of depression, self-esteem and self-efficacy failed to markedly influence uptake.

Conclusion

In conclusion, this study revealed the substantial challenges associated with implementing a fully self-directed intervention in an adolescent sample. Universal school internet-based interventions may, despite our findings, have benefits since they have the potential to minimize barriers to help seeking including stigma and a belief in self-reliance. From a preventive public health perspective these benefits should not be underestimated. However, guided interventions rather than purely self-guided approaches may be a more suitable model for the delivery of mental health interventions to adolescents.

Limitations

This study has several methodological limitations that should be taken into account when interpreting the results.

First, since MoodGYM is an open access site, students might have accessed it via a separate user name and password rather than using those sent by the research team. Thus, the number of actual MoodGYM users remains unknown, as we only are aware of those applying their assigned user names. High school students are skilled and frequent internet users. We observed during school visits that they accessed the MoodGYM web site as the presenter was talking. These limitations could compromise the results, as participants

registered as non-users could have registered beyond the research trial.

Another limitation is the selection of schools, which was not carried out randomly. Some schools agreed to participate in the MoodGYM trial after invitation whereas others declined. We are not aware of the motivation for the schools to participate. Possibly, some of the participating schools were experiencing higher levels of psychological difficulties among their students, or had limited resources to deal with mental health issues. Such factors could influence the school's decision to participate, and could affect the results of the study.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

KMG, KW and MRE participated in the design of the study, interpretation of results and helped drafting the manuscript. KL and HCBV carried out the data collection, statistical analysis and drafting of the manuscript. All authors read and approve the final manuscript.

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Paper II

Original Paper

The Clinical Effectiveness of Web-Based Cognitive Behavioral Therapy With Face-to-Face Therapist Support for Depressed Primary Care Patients: Randomized Controlled Trial

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Abstract

Background: Most patients with mild to moderate depression receive treatment in primary care, but despite guideline recommendations, structured psychological interventions are infrequently delivered. Research supports the effectiveness of Internet-based treatment for depression; however, few trials have studied the effect of the MoodGYM program plus therapist support. The use of such interventions could improve the delivery of treatment in primary care.

Objective: To evaluate the effectiveness and acceptability of a guided Web-based intervention for mild to moderate depression, which could be suitable for implementation in general practice.

Methods: Participants (N=106) aged between 18 and 65 years were recruited from primary care and randomly allocated to a treatment condition comprising 6 weeks of therapist-assisted Web-based cognitive behavioral therapy (CBT), or to a 6-week delayed treatment condition. The intervention included the Norwegian version of the MoodGYM program, brief face-to-face support from a psychologist, and reminder emails. The primary outcome measure, depression symptoms, was measured by the Beck Depression Inventory-II (BDI-II). Secondary outcome measures included the Beck Anxiety Inventory (BAI), the Hospital Anxiety and Depression Scale (HADS), the Satisfaction with Life Scale (SWLS), and the EuroQol Group 5-Dimension Self-Report Questionnaire (EQ-5D). All outcomes were based on self-report and were assessed at baseline, postintervention, and at 6-month follow-up.

Results: Postintervention measures were completed by 37 (71%) and 47 (87%) of the 52 participants in the intervention and 54 participants in the delayed treatment group, respectively. Linear mixed-models analyses revealed a significant difference in time trends between the groups for the BDI-II, ($P=.002$), for HADS depression and anxiety subscales ($P<.001$ and $P=.001$, respectively), and for the SWLS ($P<.001$). No differential group effects were found for the BAI and the EQ-5D. In comparison to the control group, significantly more participants in the intervention group experienced recovery from depression as measured by the BDI-II. Of the 52 participants in the treatment program, 31 (60%) adhered to the program, and overall treatment satisfaction was high. The reduction of depression and anxiety symptoms was largely maintained at 6-month follow-up, and positive gains in life satisfaction were partly maintained.

Conclusions: The intervention combining MoodGYM and brief therapist support can be an effective treatment of depression in a sample of primary care patients. The intervention alleviates depressive symptoms and has a significant positive effect on anxiety symptoms and satisfaction with life. Moderate rates of nonadherence and predominately positive evaluations of the

treatment also indicate the acceptability of the intervention. The intervention could potentially be used in a stepped-care approach, but remains to be tested in regular primary health care.

Trial Registration: Australian New Zealand Clinical Trials Registry: ACTRN12610000257066; <http://apps.who.int/trialsearch/trial.aspx?trialid=ACTRN12610000257066> (Archived by WebCite at <http://www.webcitation.org/6Ie3YhIZa>).

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KEYWORDS

cognitive therapy; therapy; computer-assisted; Internet; mental health; depression; randomized controlled trial; primary health care

Introduction

Overview

Depression is a highly prevalent disorder that often causes substantial functional impairment in daily life, reduction in quality of life, and increased medical service utilization [1-6]. There exist several effective psychological and pharmacological treatments for depression [7]. However, a large proportion of those suffering from this disorder receive inadequate treatment or no treatment at all [8,9]. Cognitive behavioral therapy (CBT) has proven to be as effective as pharmacotherapy in treating mild to moderate depression, with the benefit of reduced rates of relapse [10,11].

Internet-Based Treatment of Depression

The principles and techniques of CBT have been extensively disseminated through self-help books and computer- or Internet-based programs. A substantive body of research shows that Internet-based CBT can be an efficacious treatment of depression (eg, [12-15]). Research also suggests that such interventions are cost-effective compared to face-to-face treatments because they result in symptom reduction and reduced burden of disease for patients and alleviate demands on clinician time and resources [16-18].

Self-help can be self-administered or guided by a therapist, although the active involvement of the therapist in guided self-help is less extensive than in conventional psychological therapy. Studies generally show small to moderate effects of self-administered, unguided CBT in the treatment of depression [19-23], although in some studies unguided interventions have yielded large treatment effects [24,25]. Still, an increasing amount of research has pointed to the importance of support in Internet-based interventions, with interventions offering some degree of support from a professional during treatment generally showing substantially larger treatment effects than interventions involving little or no professional support [26-28]. However, this conclusion is primarily based on meta-analytic results; the results from the few studies directly comparing guided and unguided interventions are mixed [14,24,29]. Overall, guided interventions show moderate to large treatment effects for depression, and the average effect sizes for guided self-help are comparable to the effects of time-limited face-to-face treatment (eg, [13-15,30]). This is further supported by a recent meta-analysis, which found no significant differences in effect between guided self-help and face-to-face therapy [31].

MoodGYM is a free Web-based CBT program developed to prevent and treat mild to moderate depression [32]. Studies have demonstrated the effectiveness of MoodGYM in reducing symptoms of depression and anxiety among public registrants, trial participants, callers to a national helpline service, users of the UK National Health Service portal, adolescent school-based populations, and in Australian and Norwegian student samples [20,24,25,29,33-35]. Positive effects have been shown to be sustained over 12 months [36]. However, few previous trials have investigated the effect of MoodGYM combined with therapist support. A study found that the conjunction of MoodGYM and face-to-face therapy was superior to both MoodGYM alone and for some outcome measures, to time-limited face-to-face therapy alone [29]. Also the results of a cluster-randomized trial suggested positive effects of the combination of MoodGYM and support from general practitioners (GPs) compared to GP care alone [37].

Depression Treatment in Primary Health Care

Most patients with psychological problems will receive most or all of their mental health care in primary care, and findings suggest that many patients prefer to consult their GP for treatment of depression [2,38-40]. Clinical practice guidelines primarily recommend treating mild to moderate depression using psychosocial interventions [41,42], and this is also in accordance with reported patient preferences [43-45]. Nevertheless, structured psychological interventions are infrequently delivered in general practice [46-48] because of time constraints [49-51] and a lack of knowledge and competence among GPs in the delivery of evidence-based psychological interventions [51,52]. The use of CBT-based self-help resources could be a way to improve the delivery of psychological interventions in general practice. This would allow for short consultations and for the clinician to be a facilitator rather than a cognitive therapist. These features could improve feasibility in general practice, where the volume of patients is high and it is essential that interventions are brief and practical.

Aim of the Study

The current study was designed to trial a procedure for depression treatment that could be suitable for implementation in general practice. The project was planned as the first phase of research for this treatment, with the second phase focusing on further evaluation carried out in everyday general practice. The aim was to evaluate the effectiveness and acceptability of a guided self-help intervention combining the MoodGYM

program with brief face-to-face therapist support in a sample of primary care patients with mild to moderate symptoms of depression. This was investigated in a randomized controlled trial comparing the guided self-help intervention to a delayed-treatment control condition. The primary hypothesis was that therapist-supported Web-based CBT would lead to a larger reduction in depressive symptoms than the control condition. To determine if the intervention was acceptable to patients, satisfaction with treatment, adherence, and reasons for dropout were investigated.

Methods

Study Design

The study was a randomized controlled trial with balanced randomization (1:1). Participants were randomly allocated to a treatment condition comprising 6 weeks of Web-based CBT with therapist support, or to a 6-week waitlist for the same treatment during which time they could also access treatment as usual. The study was conducted at the Department of Psychology at the University of Tromsø where a small self-help outpatient clinic was established. 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 (ANU). The trial was registered in the Australian New Zealand Clinical Trials Registry (ACTRN1261000257066). The trial is reported in accordance with the CONSORT-EHEALTH [53] (see [Multimedia Appendices 1-3](#)).

Participants

Participants (N=106) were recruited between October 2010 and October 2012 from GPs, primary care nurses, and from waitlists of primary care referrals at 2 psychiatric outpatient clinics. Calculations of required sample size were based on a power of .80, significance level of .05 (2-sided), and an expected effect size of 0.6 on depressive symptoms at posttest. The estimations necessitated a sample size of 45 participants per group. A median dropout rate between 17% and 19% has been reported for computerized or Web-based treatment programs [54,55]. With a 20% expected dropout, a total sample size of 108 was required to gain sufficient power, yielding group sizes of 54 participants.

Local GPs and primary care nurses were informed about the study both verbally at practice meetings and through written information. They provided patients who they considered as mildly to moderately depressed based on clinical appraisal and/or screening instruments with written information about the project. Potentially eligible patients on waitlists for psychiatric outpatient treatment were identified by clinic staff and subsequently received information by postal mail from the research group. When informing a patient of the project, all recruiters were asked to send a notification to the research group by using a prepaid envelope. The notification simply notified the researchers that a patient had been informed of the project and did not reveal any information about the patient. Patients were provided with general information about the treatment and the aim of the project and detailed information about the methods for handling issues of privacy and anonymity. They

were informed that they could expect to commence treatment within 6 weeks of the initial contact. To participate, patients sent in a signed informed consent form providing contact details. Study inclusion criteria were: (1) age 18-65 years, (2) access to the Internet, and (3) a score between 14 and 29 on the Beck Depression Inventory-II (BDI-II), indicating mild to moderate symptoms of depression. During the first months of the study, the protocol was changed by extending the inclusion criterion on the BDI-II to include participants with scores between 10 and 40. This change was because of 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. Based on this revised criteria, 7 eligible patients were falsely excluded in the initial phase of the trial. Individuals currently undergoing CBT were excluded, whereas individuals who used antidepressant medication were stabilized for 1 month prior to evaluation of diagnostic eligibility. To maximize the external validity of the trial, a heterogeneous group of patients with depressive symptoms was included, independent of a particular diagnosis. Therefore, medical or psychiatric comorbidities only restricted inclusion when there was a need for immediate treatment of these comorbid conditions (suicidal ideation, current psychosis) or if the conditions were expected to markedly interfere with treatment of the depressive condition (alcohol or drug use disorders).

Measures

All outcome measures were based on self-report. Assessments of symptoms of depression, anxiety, and quality of life using paper-and-pencil questionnaires were completed by all participants at baseline, posttreatment, and at 6 months posttreatment (online questionnaires). The control group also completed these inventories before entering online treatment (postwaiting). BDI-II was administered before every consultation during the intervention phase.

The primary outcome measure was the BDI-II, a 21-item measure of severity of depressive symptoms during the past 2 weeks [56]. Each item is rated on a 4-point scale ranging from 0 to 3. Studies consistently support the BDI-II as a reliable, internally consistent, and valid scale for assessing depression both in psychiatric outpatients, the general population, and in primary care settings [56-58]. Several studies have found high correlations between the paper-and-pencil and the computerized/online versions of the BDI-II [59-62]. In the present study, internal consistency (Cronbach alpha) was .78 pretreatment, .93 posttreatment, and .94 at 6-month follow-up, respectively.

The secondary outcome measures consisted of the Beck Anxiety Inventory (BAI), the Hospital Anxiety and Depression Scale (HADS), and 2 measures of quality of life—Satisfaction With Life Scale (SWLS) and the EuroQol Group 5-Dimension Self-Report Questionnaire (EQ-5D)—as well as a measure of treatment satisfaction. The quality of life measures were included during the initial phase of the trial considering that the

extension of outcomes beyond symptom measures would strengthen the study.

The BAI is a 21-item measure of anxiety symptom severity [63]. Each item is rated from 0 to 3 depending on symptom severity during the past week. The inventory possesses high internal consistency and reliability, as well as robust convergent and discriminant validity [64-66]. Equivalent psychometric properties have been shown across paper-and-pencil and online formats of the questionnaire, and the 2 formats are highly correlated [59,67]. Cronbach alphas in the present study were .93 at pretreatment, .88 at posttreatment, and .92 at 6-month follow-up, respectively.

The HADS is a 14-item inventory with 2 subscales of 7 items each, measuring depression and anxiety, respectively [68]. Each item is rated on a 0 to 3 scale. The inventory has good to very good construct validity and internal consistency [68-70]. Most factor analyses confirm a 2-factor solution comprising a depression and an anxiety subscale [69]. Paper-and-pencil and Internet administration of the measure yields comparable psychometric properties, but Internet administration may overestimate scores [70,71]. In the present study, Cronbach alpha was .68 and .82 at pretreatment, .82 and .84 at posttreatment, and .87 and .86 at 6-month follow-up for the depression and anxiety subscales, respectively.

The EQ-5D is a generic questionnaire evaluating health-related quality of life [72]. The respondent marks his/her level of functioning (no problems, some problems, extreme problems) for each of 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and rates his/her health state on a visual analog scale (EQ VAS) with the endpoints labeled best imaginable health state and worst imaginable health state, respectively. For the 5 dimensions, a scoring algorithm (the MVH_A1 tariff) based on preference weights was used to aggregate an index score (EQ Index) [73]. The health states "perfect health" (no problems on any dimension) and "dead" are assigned the values of 1 and 0, respectively. The instrument has been demonstrated to discriminate between subgroups of patients with differing severities of mental illness and to capture changes in quality of life associated with improved mental health over time [74]. No significant differences have been found between scores obtained using paper and computerized modes of administration [75,76].

The SWLS measures global life satisfaction as a cognitive-judgemental process, in which individuals assess their quality of life according to their own criteria [77]. The respondent rates on a 7-point Likert scale the degree to which he/she agrees with 5 statements. Several studies confirm the scale's unidimensional structure and support its sound psychometric properties, including internal consistency, test-retest reliability, as well as convergent and discriminant construct validity [78-80]. Research indicates that Internet data on this measure is as reliable and valid as paper-and-pencil data [81]. Cronbach alpha in this study was .79 at pretreatment, .87 at posttreatment, and .93 at 6-month follow-up.

The Mini-International Neuropsychiatric Interview (MINI) is a short, structured diagnostic interview for identifying the diagnoses of the *Diagnostic and Statistical Manual of Mental*

Disorders (Fourth Edition; *DSM-IV*) and the *International Classification of Diseases, Tenth Revision (ICD-10)*. It consists of 17 modules. A comparison of MINI with other structured clinical interviews shows sensitivities and specificities above 0.70 for most diagnoses [82]. Excellent interrater reliability has been reported. The MINI Interview was used to determine psychiatric comorbidity and for excluding participants with current psychosis or suicidal ideation, as indicated by 17 points or more on the suicidal ideation module.

The Alcohol Use Disorders Identification Test (AUDIT) is a screening instrument consisting of 10 questions about alcohol use in the past 12 months, alcohol dependence symptoms, and alcohol-related problems [83]. Eight items are rated on a 5-point scale (0-4) and 2 items are rated on a 3-point scale (0, 2, 4). A large body of research confirms the favorable internal consistency, reliability, and criterion validity [83-85]. In this study, the scale was used to screen for alcohol use problems. A cutoff score of 20 was chosen to exclude patients in need of further diagnostic evaluation for alcohol dependence [85]. For participants scoring above 16, alcohol use was monitored during treatment.

The Drug Use Disorders Identification Test (DUDIT) is an 11-item screening instrument measuring patterns of substance use during the past 12 months, as well as various drug-related problems [86]. Nine items are rated on a 5-point scale (0-4) and 2 items are rated on a 3-point scale (0, 2, 4). In a sample of drug users, the scale has shown good reliability, and it predicts drug dependence with a sensitivity of 0.90 and average specificity of approximately 0.80 [86]. In the present study, the DUDIT was used to screen for drug use disorder. A cutoff score of 25 was used to exclude patients with a high probability of drug dependency.

Satisfaction with treatment was measured by 9 questions that respondents rated on a 5-point scale (1-5, very negative to very positive). The questions concerned their satisfaction with the intervention as a whole and various aspects of the self-help program and follow-up sessions. The general content of the questions was influenced by patient satisfaction questionnaires used in other studies [87-89]. However, the exact content was tailored to tap into aspects of treatment considered important for the purpose of the present investigation. The questions are described in detail in the Results section.

Treatment variables included module completion, number of sessions, treatment duration, session duration (in minutes, not including screening), and total time spent by therapists (time spent outside the consultations was not registered). User data on module completion was registered online and was denoted by a number between 0 and 4, with 0 indicating no use and 4 indicating completion of the module. For the variable time spent by therapists, the amount of missing data was considerable (51.9% for time spent on screening, 14.6% for total time); thus, these data can only be considered estimates. Total time was estimated by imputing mean screening time for missing data concerning screening duration and each individual's mean session duration for missing data from treatment sessions.

Procedure

After informed consent was obtained, participants were screened for inclusion through a face-to-face session. A computerized random number generator randomized identification (ID) numbers to the 2 groups (generated by KL). Eligible participants were given ID numbers following a chronological sequence. To ensure equal group sizes, blocked randomization with variable block sizes was used. Patients could not be blinded to group assignment, but were blinded to the status of the waitlist as a control condition.

Screening, enrollment, and treatment were carried out by 2 licensed clinical psychologists (RSH and KL) with basic CBT skills and good knowledge of the MoodGYM program. Both had less than 2 years of experience in clinical practice and no prior experience with Internet-based treatment. The therapists were not blind to the participants' group allocation. However, steps were taken to blind the evaluation of outcomes by ensuring that posttests were performed by a research assistant unaware of the participants' allocation assignment.

Intervention

Participants in both groups were free to access usual primary care treatment, which could include antidepressant medication, informal supportive therapy, or referral to specialist mental health services.

The guided self-help intervention involved 3 components: (1) The Norwegian version of the Web-based CBT program MoodGYM version 3 [90], (2) brief face-to-face therapist support, and (3) tailored emails between sessions. MoodGYM was originally developed at the Australian National University to prevent depression in young people aged between 15 and 25 years. However, data from individuals who used the English version of the program has shown that most users were aged 25 to 44 years, and that the users' average depression and anxiety scores were elevated compared to the general population [91]. Therefore, the program appears useful for older age groups than originally targeted, and for individuals with elevated levels of depressive and anxious symptomatology. The program consists of 5 modules and a personal workbook containing exercises and assessments. Module 1 through 3 focus on the cognitive model, typical patterns of dysfunctional thinking, and exercises to identify and restructure dysfunctional thinking, as well as behavioral strategies to increase engagement in positive activities. Module 4 focuses on stress and stress reduction and introduces relaxation techniques. Module 5 covers simple problem solving and typical responses to broken relationships. Each module takes approximately 45 to 60 minutes to work through. See [Figure 1](#) for screenshots from the program.

In the first session after screening, participants were introduced to the program, received their trial username and password, and were instructed to work at home with 1 module each week. After each module, participants received face-to-face support (15-30 minutes). The therapists followed a guideline script with 3 compulsory topics for every consultation: (1) monitoring of depression symptoms and discussion of changes, (2) a focus on the important topics and exercises covered by each module and the participants' experiences of working with it, and (3)

introduction of the next module and motivate participants to adhere to the treatment plan. The main focus of the therapist was on reinforcing the efforts made by participants and helping them to relate to the material and to incorporate the use of techniques from the program into their everyday living. If time permitted, participants could also bring up other topics they considered important in relation to their depression. In the concluding session, the experiences and outcomes of treatment were discussed. Therapists aimed to meet participants weekly and to complete the intervention over 7 weeks. However, the interval between sessions and the number of sessions were allowed to vary somewhat to provide flexibility in meeting individual needs. Between sessions, participants received tailored emails aiming to motivate them to work with the self-help program. The emails introduced the next module, and some contained brief advice on how to overcome depressive symptoms (eg, the importance of behavioral activation). Participants did not get a mental health record at the clinic, but a short case summary was sent to their GP (with consent from the participants). Participants considered in need of more extensive treatment throughout or after completing the trial were assisted in the process of referral to specialized mental health services. The Web-based program did not store any personally identifying information about users.

Statistical Analyses

All analyses were carried out using IBM SPSS Statistics version 19 for Windows (IBM Corp, Armonk, NY, USA), except for the power calculation which was performed using G*Power (Heinrich-Heine-Universität, Institut für Experimentelle Psychologie, Düsseldorf, Germany).

Differences between the groups on baseline characteristics were examined by performing chi-square tests for categorical variables and 1-way analysis of variance (ANOVA) for continuous variables. A logistic regression analysis with backward stepwise method was used to explore whether missing data at postintervention (not completing postintervention measures) could be significantly predicted by participant characteristics.

Results on the BDI-II and BAI were analyzed using intention-to-treat (ITT) analyses in which participants are analyzed in the group they were randomized to, irrespective of treatment adherence. Because of missing data at pretest for the remaining secondary measures (3% missing on the HADS, and 17% and 19% missing on SWLS and EQ-5D, respectively), modified ITT analysis was performed including all participants completing the measures at least once. Effects were tested by performing linear mixed-models analysis using the restricted maximum likelihood (REML) estimation procedure and an unstructured covariance matrix. Since linear mixed-models analysis can handle incomplete data, no procedure for imputation of missing data was utilized in the analysis [92]. 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. Time was coded as 0 for baseline and as number of weeks from baseline for all subsequent measures. To control for differences in treatment duration, the time frame was made comparable

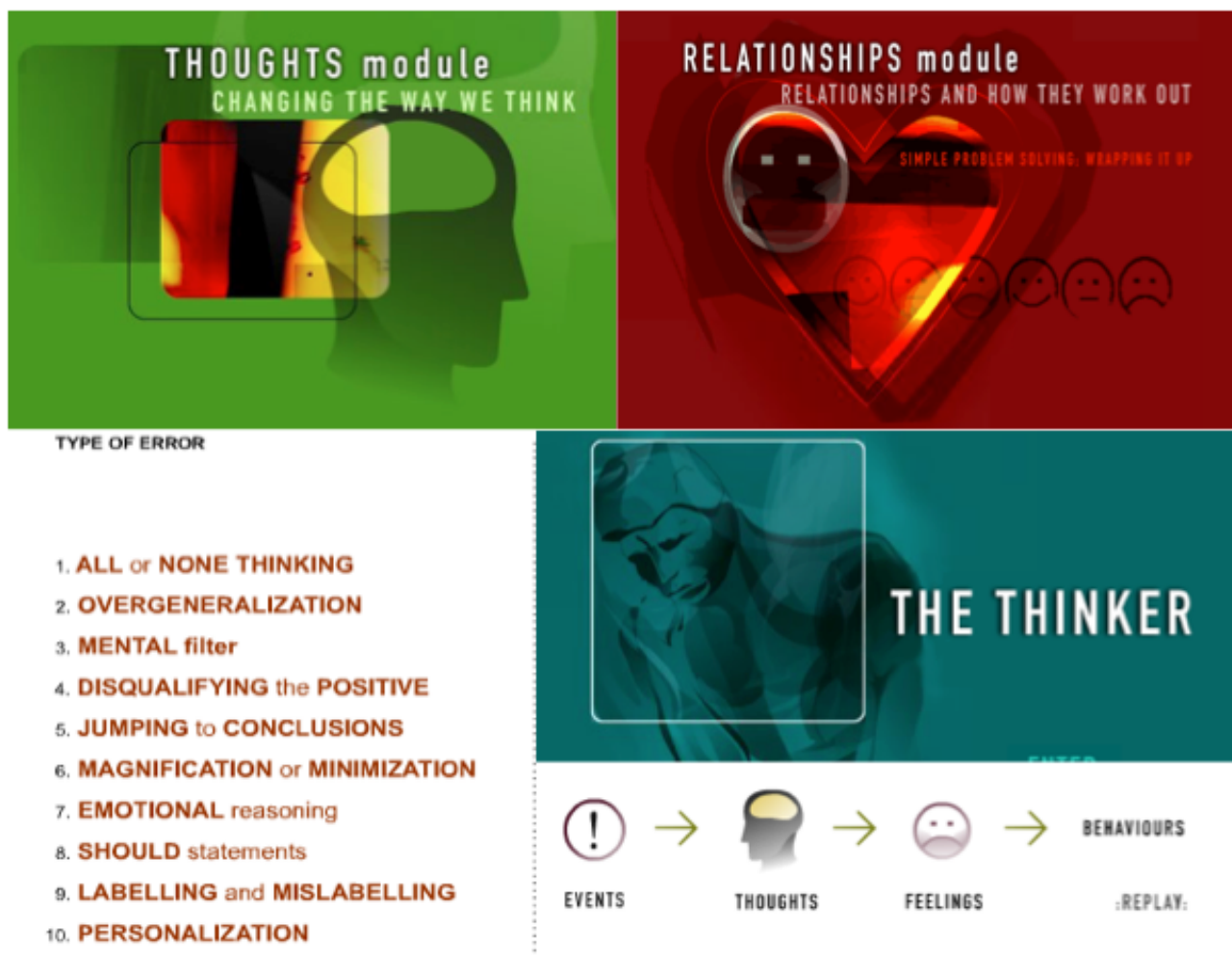
between groups by including only measures up to 7 weeks after baseline (the planned time frame for completing the intervention) for the intervention group in the main analysis. For the secondary measures and for the analysis including the 6-month follow-up data on the BDI-II, repeated measures linear mixed-models analysis was performed with occasion (baseline, posttest, 6-month follow-up) as the repeated factor. This procedure was deemed acceptable because linear regression analyses did not find treatment duration to be a significant predictor of symptom change during the treatment phase of the intervention group for any of the secondary measures (beta=-.16 to .28, $t_{29,35}=-0.91$ to 1.58, $P=.12-.92$). Scores on the last BDI-II from participants completing 5 or more weeks of treatment but missing formal posttest data (n=8), were included in the analysis, because this was considered to give a more accurate estimate of change over time.

For completers, analyses of covariance (ANCOVA) were performed with postsymptom scores as the dependent variable and preintervention symptom scores and treatment duration as covariates. Effect sizes (Cohen's *d*) were calculated for within- and between-group changes based on estimated means or beta

coefficients [93]. For the ITT analyses, calculations were based on pooled standard deviations calculated from the square root of each group's variance parameters from the mixed models analysis: the single variance estimate of the procedure with a random intercept, and the sum of the variance estimates at each time point of interest minus 2 times the covariance estimate between these time points for the repeated procedure [94,95]. For the completer analyses, the square root of the mean square error, equivalent to the pooled standard deviation, was used. A Cohen's *d* of 0.2 was considered a small effect, 0.5 a medium effect, and 0.8 or more a large effect [96].

Clinically significant changes on the BDI-II were assessed using the criteria for reliable change and cutoff points developed for the BDI by Seggar et al [97], based on the definition by Jacobson and Truax [98]. Recovery was defined as the combination of reliable improvement (a change of more than 8.5 points on the BDI-II) and endpoint symptom level below the clinical cutoff of 14.3. For those with subclinical symptoms at baseline, reliable improvement required a change of more than 4.6 points and recovery required reliable improvement plus an endpoint less than 4.1 [97]. Change scores between baseline and 7 weeks of treatment were used for the intervention group.

Figure 1. Screenshots from MoodGYM.



Results

Sample Characteristics

Figure 2 shows the flow of participants through the trial. Of the 128 individuals screened for participation, 106 (83%) were found eligible. Most participants, including 49 of 52 (94%) in the intervention group and 48 of 54 (89%) in the delayed-treatment group, were recruited from GPs. The remaining participants were recruited from waitlists at 2 outpatient clinics (n=3), from primary care nurses (n=4), and from a low-threshold clinic for youth (n=2). Postintervention measures were completed by 71% (37/52) and 87% (47/54) of the participants in the intervention and the delayed-treatment group, respectively. The 6-month follow-up assessment was completed by 42 participants (81%) in the intervention group and by 34 participants (63%) in the control group.

Group and educational level emerged as significant predictors of dropout at postintervention. The odds of dropping out before the posttest was significantly higher for participants in the intervention group relative to participants in the

delayed-treatment group (OR 3.03, 95% CI 1.08-8.47, $P=.04$), and significantly lower for participants with higher education relative to participants with a lower educational level (OR 0.36, 95% CI 0.13-0.99, $P=.048$). No other demographic or clinical variables predicted dropout at postintervention.

Table 1 shows the descriptive characteristics of the sample. For most demographic and clinical variables the 2 groups did not differ significantly at baseline ($P=.10-.90$). However, the groups differed significantly with regard to age ($P=.045$), with the intervention group being slightly older than the control group. The groups also differed on the variable comorbid anxiety ($P=.03$), with the number of participants with an anxiety disorder being significantly higher in the control group compared to the intervention group. Baseline scores on all symptom and outcome measures were comparable between the groups ($P=.13-.87$).

Further exploration of the 2 groups with regard to anxiety level as measured with BAI shows that although a higher proportion of the control group had symptoms corresponding to moderate or severe anxiety compared to the intervention group, the distribution across the categories minimal, mild, moderate, and severe anxiety did not differ significantly ($P=.29$).

Figure 2. Flow of participants through the trial.

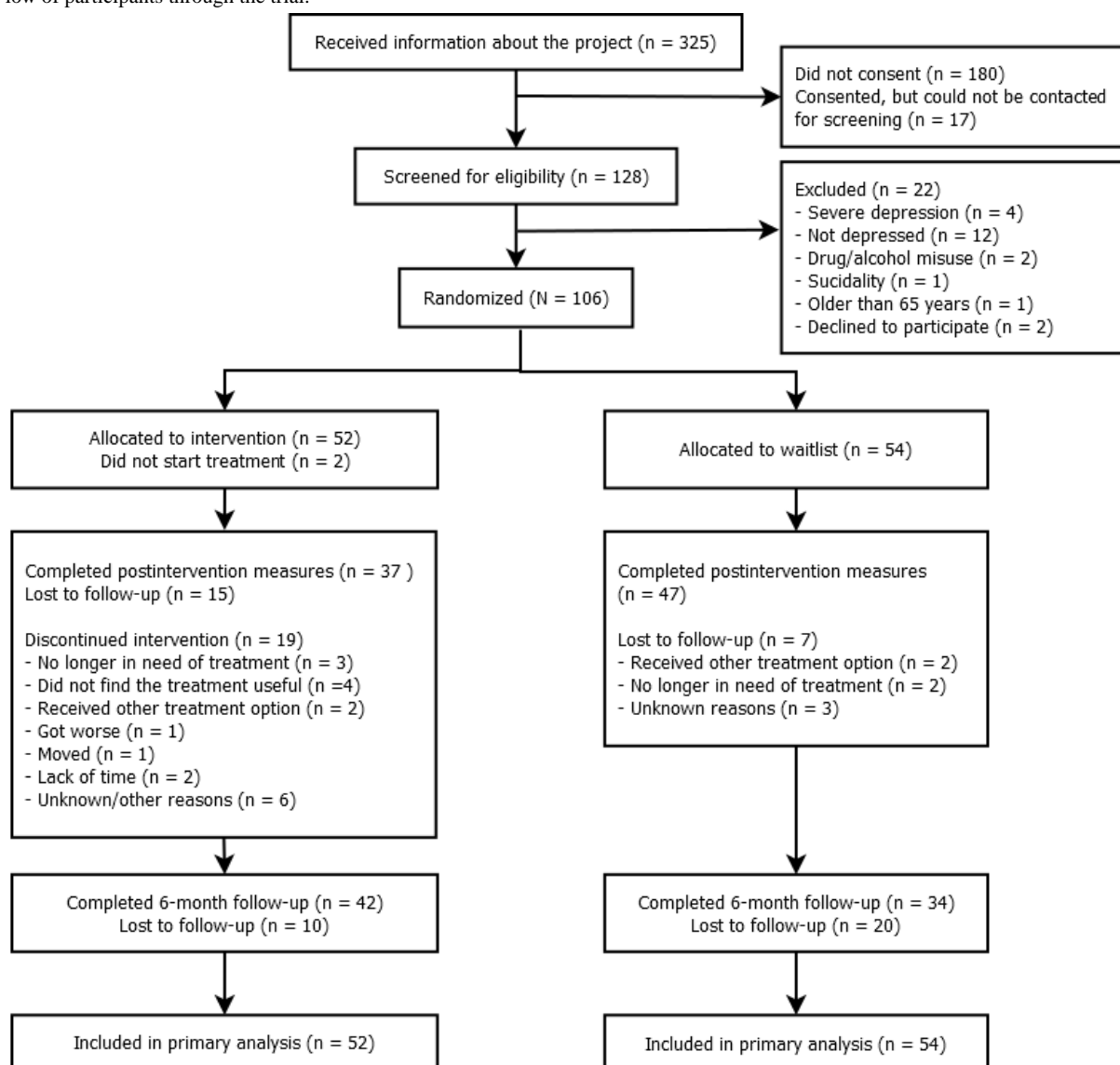


Table 1. Participant characteristics at baseline.

Participant characteristics	Intervention (n=52)	Waitlist (n=54)	Total (N=106)
Gender, n (%)			
Male	15 (28.8)	14 (25.9)	29 (27.4)
Female	37 (71.2)	40 (74.1)	77 (72.6)
Age (years)			
Mean (SD)	38.3 (12.2)	33.9 (9.9)	36.1 (11.3) ^a
Range	19 - 63	18 - 58	18 - 63
Marital status, n (%)			
Married/living together	28 (53.8)	31 (57.4)	59 (55.7)
Separate living	2 (3.8)	4 (7.4)	6 (5.7)
Divorced	3 (5.8)	5 (9.3)	8 (7.5)
Single	19 (36.5)	14 (25.9)	33 (31.1)
Highest educational level, ^b n (%)			
Compulsory school (9 or 10 years)	6 (11.5)	1 (1.9)	7 (6.6)
High school	16 (30.8)	26 (48.1)	42 (39.6)
University, 3 years	17 (32.7)	14 (25.9)	31 (29.2)
University, ≥5 years	13 (25.0)	12 (22.2)	25 (23.6)
Employment, n (%)			
Employed (full- or part-time)	37 (71.2)	37 (68.5)	74 (69.8)
Student	5 (9.6)	6 (11.1)	11 (10.4)
Long term sick	7 (13.5)	3 (5.6)	10 (9.4)
Homemaker	1 (1.9)	5 (9.3)	6 (5.7)
Unemployed	2 (3.8)	3 (5.6)	5 (4.7)
Sick leave (employed sample)	18 (48.6)	21 (56.8)	39 (52.7) ^c
Present treatment, ^d n (%)			
Medication	13 (25.0)	7 (13.0)	20 (18.9)
Other treatment	7 (13.5)	4 (7.4)	11 (10.4)
None	36 (69.2)	44 (81.5)	80 (75.5)
Treatment history, ^e n (%)			
Earlier	32 (61.5)	30 (55.6)	62 (58.5)
None	18 (34.6)	23 (42.6)	41 (38.7)
Depression current, ^f n (%)	26 (50.0)	25 (46.3)	51 (48.1)
Number of major depressive episodes, ^g n (%)			
0	5 (9.6)	6 (11.1)	11 (10.4)
1	16 (30.8)	18 (33.3)	34 (32.1)
2 - 4	14 (26.9)	15 (27.8)	29 (27.4)
≥5	14 (26.9)	11 (20.4)	25 (23.6)
Comorbidity, ^h n (%)			
Anxiety	12 (23.1)	23 (42.6)	35 (33.0) ^a

Participant characteristics	Intervention (n=52)	Waitlist (n=54)	Total (N=106)
Other axis-I disorder	1 (1.9)	4 (7.4 %)	5 (4.7)
Symptom measures, ⁱ mean (SD)			
AUDIT	4.8 (3.8)	5.4 (4.3)	5.1 (4.0)
DUDIT	0.4 (2.2)	0.7 (2.5)	0.6 (2.3)
Internet Use, ^j n (%)			
Daily	50 (96.2)	42 (77.8)	92 (86.8)
Weekly	0 (0.0)	3 (5.6)	3 (2.8)

^a $P < .05$.

^b0.9% missing.

^c36.8% of the total sample.

^dMedication is antidepressants; other treatment is psychological therapy other than CBT.

^e2.8% missing.

^fMajor depressive episode fulfilling *DSM-IV* criteria.

^g6.6% missing.

^hAnxiety includes panic disorder, agoraphobia, social phobia, and generalized anxiety; other axis-1 disorders include bipolar disorder, obsessive-compulsive disorder, bulimia, and posttraumatic stress disorder.

ⁱAUDIT: Alcohol Use Disorders Identification Test, 0.9% missing; DUDIT: Drug Use Disorders Identification Test, 0.9% missing.

^j10.4% missing.

Attrition and Adherence

Of the 52 participants in the intervention group, 31 (60%) adhered to the treatment program in that they completed MoodGYM and attended at least 7 sessions. Total nonadherence was 40% (21/52). Reasons for nonadherence are summarized in [Figure 2](#). Overall, the sample starting treatment (n=50) completed a mean of 3.8 (SD 1.7) of the 5 modules, attended a mean of 7.2 (SD 2.3) sessions, with average session duration of 27.7 (SD 6.2) minutes. The average number of weeks in treatment was 11.3 (SD 7.2). Total time spent by therapists ranged from 70 to 506 minutes (mean 242.1, SD 96.6). A previous study found that versions of the MoodGYM program encompassing Module 2 (extended CBT) were associated with greater improvements than versions excluding this module [91]. This suggests that Module 2 may be a particularly important treatment component. Of the 50 participants starting treatment, 86% (n=43) completed 2 or more modules, indicating that they may have completed enough of the treatment program to generate beneficial outcomes.

Depression and Anxiety Symptoms

[Table 2](#) depicts the preintervention, postintervention, and 6-month follow-up means and standard deviations for each group, as well as within-group and between-group effect sizes. The ITT analysis for the primary outcome measure, BDI-II, revealed a significant time by treatment group interaction ($F_{1,244.83}=9.55$, $P=.002$, $d=0.65$). There was also a significant effect of time ($F_{1,245.37}=11.87$, $P=.001$). Both groups experienced significant improvements of depressive symptoms during the intervention phase, but this improvement was significantly larger in the intervention group compared to the delayed-treatment group. Because most of the intervention group had not yet completed treatment at 7 weeks, the analysis was repeated using

scores from the intervention group up to 8, 10, 12, and 14 weeks. The interaction term remained significant ($F_{1,268.81-333.62}=6.34-10.88$, $P=.01-.001$, $d=0.54-0.67$). Repeated linear mixed-models analysis also found significant different time trends for the groups between posttest and 6-month follow-up ($t_{81.17}=2.88$, $P=.005$). During this time, the delayed-treatment group had received treatment, and pairwise comparisons indicated a significant decrease in symptoms in this group ($P=.001$), whereas level of depressive symptoms in the intervention group remained stable ($P=.56$).

The ITT analysis for the BAI revealed no significant interaction between treatment group and occasion ($F_{1,84.31}=0.37$, $P=.69$). Pairwise comparisons showed that both groups improved significantly between baseline and posttest ($P=.007$ and $P=.02$ for the intervention and control group, respectively; see [Table 2](#)). Between posttest and 6-month follow-up, the control group further improved ($P=.04$), whereas the intervention group remained unchanged ($P=.36$). Analyses for the HADS subscales yielded significant group by occasion interactions for both the depression subscale ($F_{1,78.05}=14.68$, $P<.001$) and the anxiety subscale ($F_{1,78.07}=8.10$, $P=.001$). Pairwise comparisons for both subscales found that the intervention group, but not the control group, reduced their scores significantly between pretest and posttest ($P<.001$ and $P=.46$, respectively, for the depression subscale and $P<.001$ and $P=.44$, respectively, for the anxiety subscale; [Table 2](#)). Between posttest and 6-month follow-up, the control group experienced a significant reduction in both depressive and anxiety symptoms ($P=.001$ and $P<.001$, respectively), whereas scores did not change significantly for the intervention group for the depressive subscale ($P=.07$) or for the anxiety subscale ($P=.80$).

For all reported ITT and modified ITT analyses, baseline anxiety symptoms on the BAI and age were included as covariates, with the exception that baseline BAI scores were not included as a covariate in the analysis of BAI. The effect of BAI scores was consistently significant ($P=.02$ to $P<.001$). The effect of age was significant in 2 of 8 models ($P=.008-.03$).

Completer Analyses

The results of the ANCOVA revealed the same pattern of results. There was a significant effect of group on posttest level of depressive symptoms measured with BDI-II ($n=84$; $P<.001$, $d=1.09$) and with HADS ($n=76$; $P=.002$, $d=0.95$), and level of anxious worry as measured with HADS ($n=76$; $P=.002$, $d=0.97$) after controlling for the effect of baseline symptoms and treatment duration. The results were not significant for anxiety as measured with BAI ($n=83$; $P=.47$, $d=0.20$). Thus, for depression and anxiety measured with HADS, the groups differed significantly in posttest scores after controlling for differences in preintervention scores and treatment duration. Baseline symptoms were significantly related to posttest symptoms for all measures ($P<.001$), whereas treatment duration did not significantly affect outcome ($P=.19-.92$).

Quality of Life

For the SWLS, the modified ITT analysis showed a significant interaction between treatment group and occasion ($F_{1,75.75}=8.49$, $P<.001$). Pairwise comparisons found a significant increase in satisfaction for the intervention group from pretest to posttest ($P<.001$), but no such change for the delayed-treatment group ($P=.52$; see Table 2). Between posttest and 6-month follow-up, there was a significant increase in life satisfaction in the control group ($P=.01$), whereas the intervention group did not experience significant changes ($P=.08$). The analyses for EQ Index yielded an overall significant difference in time trends between the groups ($F_{1,67.42}=3.55$, $P=.03$). Between pretest and posttest, there was no significant interaction between treatment group and occasion ($t_{68.82}=-1.00$, $P=.32$), with both groups improving at comparable rates over time. However, there was a significant group by occasion interaction between posttest and 6-month follow-up ($t_{63.96}=-2.66$, $P=.01$, with the control group showing significant improvement ($P=.02$), whereas there were no significant changes in the intervention group ($P=.18$). For the EQ VAS, the overall interaction between group and occasion was not significant ($F_{1,71.32}=2.25$, $P=.11$). Between pretest and

posttest both the intervention group ($P<.001$) and the control group ($P=.03$) experienced significantly improved self-reported health state (Table 2), but the interaction between group and occasion was not significant ($t_{66.07}=-1.94$, $P=.06$). Between posttest and 6-month follow-up, pairwise comparisons showed a slight, but nonsignificant, improvement in the control group ($P=.06$), whereas scores in the intervention group remained stable ($P=.74$).

Completer Analyses

Similar results were found for the completer analyses, in which ANCOVA showed a significant effect of group for the SWLS ($n=66$) after controlling for baseline levels of life satisfaction and treatment duration ($P=.006$, $d=0.86$). There was no significant effect of group on health-related quality of life at posttest, EQ Index ($n=63$; $P=.56$, $d=0.18$), or health state at posttest, EQ VAS ($n=61$; $P=.11$, $d=0.52$), despite a moderate effect size for the latter. The effect of baseline scores was significant for all measures ($P\leq.002$). There were no significant effects of treatment duration ($P=.14-.99$).

Clinical Significance of Changes in Depressive Symptoms

Table 3 presents data on clinically significant change on the BDI-II, based on scores at 7 weeks for the intervention group. The ITT procedure was used (classifying all who did not start treatment or did not complete their waitlist period as nonresponders). The results of the chi-square tests for the full sample and the sample with BDI scores above clinical cutoff show that significantly more participants recovered in the intervention group compared to the delayed-treatment control group. Conversely, a significantly smaller proportion of the intervention group experienced no change within the intervention period. For the sample fulfilling the criteria for a major depressive episode at baseline, the same trend was evident, but the difference in rate of recovery did not reach significance. The rates of improvement and deterioration were similar in the 2 groups for all analyses. The same analysis carried out after excluding participants ($n=8$) who during the waitlist or intervention period started or increased their dosage of antidepressant medication, or commenced other psychological treatment, produced similar patterns of results. At 7 weeks of treatment 37 of 52 participants (71%) in the intervention group had completed 2 or more modules, whereas 15% ($n=8$) had completed treatment.

Table 2. Estimated means (EM),^a observed means (OM), observed standard deviations (SD), standard deviations based on linear mixed-models variance estimates (SDm), and effect sizes from pretreatment (pre) to posttreatment (post) and pretreatment to 6-month follow-up (6 m) for the intervention and the delayed-treatment control group.

Measures	Intervention (n=52)				Delayed treatment (n=54)				Effect size (Cohen's <i>d</i>) ^b					
	EM	OM	SD	SDm	EM	OM	SD	SDm	Pre-post			Pre-6 m		
									B	Wi	Wdt	B	Wi	Wdt
BDI-II									0.65	-0.98	-0.65	-0.12	-0.81	-1.02
Pretreatment	21.37	21.13	6.85		21.85	22.27	6.74							
7 weeks	15.15 ^c	14.20 ^c	8.15	5.86	19.07	18.63	8.64	4.63						
6 months	13.39	12.45	9.32	10.35	11.86	12.82	10.98	9.56						
BAI									0.08	-0.41	-0.35	-0.12	-0.48	-0.65
Pretreatment	12.23	12.05	11.10		15.10	15.33	10.90							
Posttreatment	8.80	8.36	9.26	8.21	12.30	12.83	8.10	8.03						
6 months	7.46	7.07	6.61	10.37	9.19	9.41	9.79	9.05						
HADS Depression									1.10	-1.17	-0.11	-0.10	-0.53	-0.65
Pretreatment	8.21	8.08	2.92		7.40	7.61	3.13							
Posttreatment	4.67	4.24	2.61	3.13	7.07	7.19	3.63	2.70						
6 months	5.91	5.76	4.05	4.29	4.66	4.85	3.77	4.16						
HADS Anxiety									0.74	-0.60	0.13	-0.13	-0.52	-0.55
Pretreatment	9.14	8.81	3.95		9.15	9.59	4.59							
Posttreatment	7.15	6.74	3.69	3.29	9.52	10.07	4.18	3.04						
6 months	6.99	6.57	4.16	3.99	6.40	6.94	4.79	4.88						
SWLS									0.85	0.85	0.12	-0.12	0.35	0.52
Pretreatment	16.41	16.54	5.25		16.83	16.36	5.75							
Posttreatment	20.38	21.46	6.04	4.60	17.28	17.21	5.02	3.69						
6 months	18.66	19.00	6.63	6.42	19.79	20.00	6.91	5.52						
EQ-5D VAS									0.47	0.79	0.42	-0.01	0.71	0.55
Pretreatment	58.59	59.13	18.68		56.01	54.93	17.87							
Posttreatment	71.13	73.88	15.30	16.35	61.67	60.77	17.09	13.10						
6 months	70.12	71.79	14.65	16.04	67.78	66.41	20.86	21.56						
EQ-5D Index									0.22	0.59	0.26	-0.33	0.26	0.74
Pretreatment	0.63	0.63	0.23		0.61	0.60	0.25							
Posttreatment	0.75	0.80	0.17	0.24	0.68	0.67	0.24	0.27						
6 months	0.70	0.72	0.26	0.30	0.78	0.77	0.20	0.21						

^aEstimated means (except for BAI) are adjusted for the covariates baseline BAI score and age.

^bB: between-group effect size; Wi: within-group effect size for the intervention group; Wdt=within-group effect size for the delayed-treatment group.

^cEstimated mean after completing treatment=12.43, observed mean after completing treatment=11.34.

Table 3. Proportion of participants reaching the criteria for clinically significant improvement on the Beck Depression Inventory-II (BDI-II) at 7 weeks of treatment and results of chi-square tests (χ^2).

Treatment response	Full sample, n (%) (N=106)		Baseline BDI-II above clinical cutoff, ^a n (%) (n=90)		Current major depressive episode diagnosis, n (%) (n=51)				
	Intervention (n=52)	Control (n=54)	χ^2_1	Intervention (n=42)	Control (n=48)	χ^2_1			
Recovered	17 (32.7)	5 (9.3)	8.8 ^b	15 (35.7)	5 (10.4)	8.3 ^b	8 (30.8)	3 (12.0)	2.7
Improved	8 (15.4)	5 (9.3)	0.9	5 (11.9)	4 (8.3)	0.3	6 (23.1)	3 (12.0)	1.1
No change	26 (50.0)	41 (75.9)	7.7 ^b	21 (50.0)	38 (79.2)	8.4 ^b	11 (42.3)	18 (72.0)	4.6 ^c
Deteriorated	1 (1.9)	3 (5.6)	0.3	1 (2.4)	1 (2.1)	0.01	1 (3.8)	1 (4.0)	0.001

^aBDI-II>14.^b $P<.01$.^c $P<.05$.

Therapist Effects

Therapist effects were investigated by looking at the interaction between therapist and time for the intervention group. The analyses indicated a significant difference between the 2 therapists when analyzing BDI-II scores up to 7 and 8 weeks of treatment ($P=.03-.04$). This effect no longer reached significance when including scores up to 10, 12, and 14 weeks of treatment ($P=.05-.32$). The analyses did not yield differential treatment effects across the 2 therapists for the HADS depression subscale ($P=.87$), nor for any other outcome measure ($P=.50-.94$). An exploratory linear regression analysis showed that symptom change in the intervention group was not significantly predicted by the total time spent by the therapists for any outcome measure (beta=-.12 to .26, $t_{29,48}=-0.81$ to 1.52, $P=.14-.96$).

Treatment Satisfaction

Table 4 shows the response frequencies for questions regarding satisfaction with the treatment. The results are reported for participants in both groups (intervention group: n=39; delayed-treatment control group: n=26) who completed the full treatment or parts of it. Overall satisfaction with the treatment was high, with 89% (58/65) giving the intervention as a whole a rating of 4 or 5 on a scale with 5 being very satisfied (see Table 4). Most participants also indicated that they would recommend the combined intervention to a friend with a similar problem. The ratings of the MoodGYM program were positive,

but somewhat more moderate with between 50% and 60% giving clearly positive ratings (4 or 5 on the 5-point scales, see Table 4) to the benefit of the program, the usefulness of the exercises, and the relevance of the thematic content, and none rating the program as not useful or relevant. The benefit of the treatment sessions and the relationship with the therapist were rated positively by more than 90% (60/65 and 64/65, respectively) of the participants.

Service Use and Work Status After Treatment

Of the 76 participants who completed the follow-up assessment, 45% (19/42) of participants in the intervention group and 38% (13/34) of participants in the control group had received treatment for mental health problems during the 6-month follow-up period. Two participants (3%) had been hospitalized, 19 (25%) had used antidepressant medication (15 currently using), 26 (34%) had received psychological treatment individually or group therapy, and 16 (21%) had received treatment from their GP. Of the 19 participants reporting use of antidepressants, only 6 had commenced this treatment during the follow-up period.

With regard to work status, 6 of 42 respondents (14%) in the intervention group reported that they had been on sick leave at some point in the follow-up period due to feeling tired, stressed, or experiencing mental health problems, whereas 9 of 34 respondents (26%) in the control group reported sick leave during this period.

Table 4. Response frequencies regarding satisfaction and experiences with the treatment (n=65).

Item	Satisfaction/experience scale				
	1	2	3	4	5
Overall satisfaction with the treatment					
Scale	Very dissatisfied				Very satisfied
n (%)	0 (0.0)	0 (0.0)	7 (10.8)	40 (61.5)	18 (27.7)
Change in symptoms					
Scale	Much worse		Neither nor		Much improved
n (%)	0 (0.0)	2 (3.1)	16 (24.6)	26 (40.0)	21 (32.3)
Would recommend the treatment to a friend with a similar problem					
Scale	Definitely not				Yes, definitely
n (%)	0 (0.0)	0 (0.0)	4 (6.2)	21 (32.3)	40 (61.5)
Benefit of using MoodGYM					
Scale	No benefit				Highly beneficial
n (%)	0 (0.0)	4 (6.2)	24 (36.9)	32 (49.2)	5 (7.7)
The usefulness of the exercises in MoodGYM					
Scale	Not useful				Very useful
n (%)	0 (0.0)	5 (7.7)	23 (35.4)	28 (43.1)	9 (13.8)
Relevance of the thematic content of MoodGYM ^a					
Scale	No relevance				Highly relevant
n (%)	0 (0.0)	I: 4 (10.3) C: 1 (3.8)	I: 20 (51.3) C: 6 (23.1)	I: 10 (25.6) C: 13 (50.0)	I: 5 (12.8) C: 6 (23.1)
Benefit of the follow-up sessions					
Scale	No benefit				Highly beneficial
n (%)	0 (0.0)	0 (0.0)	5 (7.7)	34 (52.3)	26 (40.0)
Satisfaction with the number of sessions					
Scale	Too few		Just enough		Too many
n (%)	1 (1.5)	6 (9.2)	55 (84.6)	3 (4.6)	0 (0.0)
Relationship to the therapist					
Scale	Very negative				Very positive
n (%)	0 (0.0)	0 (0.0)	1 (1.5)	14 (21.5)	50 (76.9)

^a $P < .05$, frequencies reported separately for the intervention (I) and delayed-treatment control (C) groups.

Discussion

Principal Findings

The results of the present study indicate that a guided self-help intervention combining the MoodGYM program with face-to-face therapist support can be effective in reducing depressive symptoms for a sample of mildly to moderately depressed individuals recruited from primary care. The intervention also had significant positive effects on symptoms of anxious worry, and participants experienced significant improvements in global satisfaction with life. At 6-month follow-up, positive gains in terms of reduction of depressive and anxious symptoms were largely maintained, whereas improvements in life satisfaction were partly maintained. The

rate of nonadherence (40%) was moderate and the evaluations of the treatment as a whole were predominately positive.

These findings are consistent with previous research in which favorable outcomes have been shown for treatments combining MoodGYM and face-to-face support from a professional [29,37]. The trials are not fully comparable, though, because the present study used a delayed-treatment control condition, whereas both previous trials used comparison groups that received more active treatments. This makes direct comparisons of between-group effect sizes difficult. However, the effect of guided self-help for mild to moderate depression using other Internet-based programs has generally been in the moderate to large range [19,27]. The magnitude of the between-group effect size on depression measured with BDI-II in this study was within this

range, but somewhat below average, whereas the effects on SWLS and on depression and anxiety measured with HADS were commensurable to effects found previously for similar measures [12-14,27,99,100]. Also, the rates of recovery and of improvement and recovery combined (33% and 48%, respectively) are in good accordance with results of prior investigations, in which clinically significant improvement and recovery have varied between 25% and 50% [12,14,15,30,100]. The nature of the guidance provided in these studies is somewhat heterogeneous, with some studies, such as the present study, defining guidance as active engagement in the therapeutic process, whereas several other studies have focused primarily on providing feedback and encouragement. However, there is no indication of significantly differential treatment effects depending on the nature of the guidance to date [19,100]. The somewhat smaller between-group differences of the present study must be seen in relation to the relatively high degree of positive change in the control group, with effect sizes being in the small to moderate range for several measures (see Table 2). Almost half of the sample did not fulfill the criteria for a major depressive episode on enrollment in the trial, and previous studies of minor depression have shown high rates of placebo response in primary care patients [101] and substantial likelihood of spontaneous remission in the general population [102]. In the present study, the control group was also free to access usual treatment in general practice during the waiting period. In addition, prior to entering the study control participants participated in a screening session in which they had the opportunity to describe their problems, something that could have a therapeutic effect per se. These factors may partly explain the positive gains in the delayed-treatment group and, hence, the modest differences in outcome between the groups.

The results of the 6-month follow-up are also encouraging in that improvements of depression and anxiety symptoms were largely maintained, and the number of participants reporting sick leave due to mental health problems was substantially smaller during follow-up compared to baseline (20% and 53%, respectively). The proportion of participants using antidepressant medication at baseline and during the follow-up period was comparable, but there was a considerable increase in the number of participants who had accessed psychological treatment during follow-up (34%) compared to baseline (10%). This is, however, not surprising because many participants had already been referred to such treatment when entering the project, but may still have contributed to further improvements and maintenance of symptom reduction. For some measures, particularly the depression subscale of the HADS and the SWLS, there was a tendency toward an increase in symptoms and lowering of life satisfaction during the follow-up period. The inclusion of booster sessions after the completion of the active treatment phase could be a measure to accomplish continued use of helpful techniques and skills and the prevention of symptom relapse. Further research is needed to clarify this issue.

The results of the present trial are also consistent with research suggesting that MoodGYM, despite its main focus on depressive thought content, can have significant positive effects on anxiety symptoms [29,35,103]. In the present study, significant treatment effects were found for anxiety symptoms measured with HADS,

but not with BAI. The questions on the HADS focus primarily on symptoms such as worry, nervousness, and not being able to relax. This is in good accordance with the core symptoms of the Goldberg Anxiety Scale [104], which has been used in several studies with MoodGYM. In comparison, the BAI incorporates both these subjective anxiety symptoms, as well as 3 more somatic symptom clusters: neurophysiological, autonomic, and panic [63]. The MoodGYM program focuses primarily on restructuring dysfunctional thinking and does not include an introduction to the physiology of anxiety or other treatment techniques for anxiety. Thus, the present results, with the program showing effects on anxious worry but not on more physiological symptoms, seem to be in-line with the thematic focus of the program.

The adherence rate in the present study is comparable to that observed in other online guided interventions, in which adherence varied between 55% and 75% [13,14,23,30,99]. The rates of adherence are also comparable to those seen in other psychotherapy research and in regular clinical practice [105-107]. This level of adherence in the current study, and the high proportion (89%) of completers reporting being satisfied with the treatment, points to the acceptability of the intervention. The evaluation of the MoodGYM program was somewhat more moderate with between 50% and 60% allocating an unambiguous positive rating to the benefit and relevance of the program. This moderate level of satisfaction in the present adult sample may arise from the fact that the MoodGYM program was originally targeted at youth and young adults. Although the therapists emphasized the applicability of the principles for all age groups when introducing the intervention, and many participants managed well to make use of the content, participants frequently characterized the program as “too young.” As these aspects of treatment were not formally measured, these factors require further investigation to be properly elucidated.

Strengths and Limitations

The current study was designed to trial a treatment procedure prior to its evaluation in general practice. Therefore, we sought to ensure a high level of internal validity while at the same time aiming to increase external validity by reflecting the heterogeneity of patients in real clinical practice. One strength of the study is the relatively heterogeneous sample of participants with regard to the range of depression and anxiety symptoms. There was also substantial comorbidity with anxiety disorders, although lower than rates found in population-based studies [108,109]. The fact that 83% of screened participants were found eligible also indicates that the sample is representative of those who opted for this choice of treatment.

An overarching focus in designing the intervention was feasibility for implementation in general practice. Studies have suggested that GPs may find the implementation of CBT techniques too time-consuming [49,110]. Therefore, sessions were primarily supportive and structured by the Web-based program. To allow for flexibility and increase feasibility, a guideline script rather than a more comprehensive manual guided each consultation. This lack of rigid standardization may have introduced some variability in treatment fidelity.

Blinding of participants was not possible for obvious reasons in this trial. However, the control group was blinded to the status of the waitlist as a control condition. Waitlists for treatment is the norm in Norwegian mental health care, and the short wait for the present treatment compared to other treatment options, may have minimized negative effects (“nocebo effects”) in the control group.

The present study also has several limitations that need to be addressed. First, the design of the study with only 1 intervention group receiving a compound of intervention elements does not allow for tests of the specific contribution of MoodGYM and the face-to-face consultations. Second, the lack of allocation concealment and blinding, and the role of the first and second authors as therapists in the trial introduced a risk of bias that may have inflated the treatment effects. Unfortunately, resource constraints prevented the use of independent therapists. The use of self-report measures rather than therapist assessments does alleviate this problem to some degree. Biased outcome assessments were further prevented by ensuring that a research assistant without knowledge of the participants’ condition assignment collected posttest data. Third, the sole reliance on self-report is a limitation in itself. Independent preassessments and postassessments by a clinician blinded to condition allocation would have been preferable and would have strengthened the results. Fourth, at preintervention there was a lack of comparability in diagnosed anxiety between the groups, with a significantly larger proportion of the control group fulfilling the criteria for an anxiety disorder. Despite this difference in diagnosed anxiety, scores on 2 different anxiety scales (HADS and BAI) were not significantly different, which suggests comparable anxiety levels in the groups. To minimize the effect of differences in anxiety, all primary analyses were controlled for anxiety level as measured with BAI, for which the observed difference was most significant. Fifth, the use of an unequal number of assessments of depressive symptoms in the 2 groups, with the intervention group having weekly assessments and the control group only completing a pretest and posttest, may have resulted in more favorable effects in the intervention group because of measurement effects. Previous studies of nonclinical samples have indicated that scores on the BDI tend to decrease with repeated administration [111,112]. Whether this holds for clinical samples is less certain. In this study, the effect of repeated measurement cannot be clearly distinguished from the treatment effect. However, comparable effects were also found for symptoms assessed only preintervention and postintervention in both groups. This indicates that the treatment had beneficial effects over and above possible measurement effects. Still, in light of this limitation, the results must be interpreted with caution. Sixth, the use of different administration formats for the assessments of the treatment phase and follow-up, (paper-and-pencil vs online questionnaires, respectively) can potentially introduce measurement bias. Although the 2 formats correlate highly, a previous study reported a significant difference in mean scores on the BDI-II and BAI, which makes switching of formats problematic [59]. Despite this limitation, the results should not be considered weakened for most measures because the direction of differences has generally suggested that online versions tend to inflate estimations of symptom severity and lower ratings of

quality of life [59,71,76], with the exception of BAI, for which Carlbring et al [59] found that means on the online version were lower compared to the paper-and-pencil version. The reliability of the 6-month follow-up results for the BAI may, therefore, be limited. Seventh, the multiplicity of outcomes increases the risk of type I errors. However, the main findings of the present trial would still be significant when employing the Bonferroni correction. This indicates the robustness of the findings. Finally, although the heterogeneity of the sample and the recruitment from primary care is a strength, the generalizability of the results is uncertain because the sample was a self-selected group. Based on the notifications by the GPs when informing a patient of the study, the estimated uptake (meeting up for screening) was 39% (128 of 325 who received information), which is slightly greater than the median uptake for computerized CBT [55]. Considering the extra barriers imposed by the research activities, this uptake rate is relatively high and indicates the possible acceptability of this treatment among depressed primary care patients. It also strengthens the generalizability of the results, by indicating that the self-selected group may be representative of a considerable proportion of the targeted group of primary care patients.

Potential Clinical Implications and Further Research

The positive treatment effects found for the intervention in the present study are encouraging and suggest that this intervention may have a potential for use in a stepped-care approach. The demand for mental health treatment is higher than what can be met by the current number of trained clinicians [113]. To increase availability of treatment, beneficial interventions must be delivered as efficiently as possible to as many people as possible. The present intervention is time-limited, and because the CBT elements are largely delivered by the program, primary care therapists with some training in CBT and MoodGYM, should be able to provide adequate guidance. In fact, studies show that guidance may be delivered effectively not only by trained clinicians, but also by mental health workers with limited experience and by computer technicians [114,115]. Thus, dissemination of the current intervention to regular primary care could be a step toward increasing access to psychological therapies. However, the moderate ratings of the benefit and relevance of the content of the Web-based program by an adult population points to the need for a variety of Web-based tools to make such treatments acceptable for a wider audience.

For practical reasons, we chose to use psychologists for this first evaluation. Therefore, further research is needed to determine if the present intervention would be as effective and acceptable in regular clinical practice when delivered by GPs or other primary care therapists. It may also be noted that the present intervention was more time-intensive than most other guided self-help interventions. However, since the role of the clinician was mainly supportive and facilitative and the main therapeutic input was delivered through a standardized treatment package, the intervention was regarded conceptually as a guided self-help intervention [31]. Similar effects have been found for low- and high-intensity guided Internet-based psychotherapy [19]. Further research should investigate if the present intervention with more limited therapist support could yield similar effects.

Conclusion

Despite its limitations, the present study indicates that an intervention combining the MoodGYM program with therapist support can be an effective treatment of depression in a sample of primary care patients. The intervention not only alleviates depressive symptoms, but also has positive and significant effects on symptoms of anxious worry and global satisfaction with life. Positive gains in terms of reduction of depressive and anxious symptoms were largely maintained at 6-month follow-up, and improvements in life satisfaction were partly maintained. Moderate rates of nonadherence and predominately

positive evaluations of the treatment as a whole also indicates the acceptability of the intervention. The intervention was designed to be suitable for implementation in primary health care, and could have a potential for use in a stepped-care approach. However, further research is necessary to determine whether it is equally effective when delivered in regular primary health care and whether the inclusion of booster sessions could further improve symptom maintenance. Further research is also needed to investigate whether the intervention is truly acceptable for the wider group of primary care patients and whether it is considered feasible and acceptable by GPs or other primary care therapists.

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Conflicts of Interest

KG is one of the authors of the MoodGYM intervention evaluated in the trial, and works for The Australian National University who provides free access to the MoodGYM program. KW and ME contributed in the process of translating MoodGYM into Norwegian. RSH, KL, TW, and NK have no financial or nonfinancial interests to declare in relation to this study.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [53].

[PDF File (Adobe PDF File), 999KB - [jmir_v15i8e153_app1.pdf](#)]

Multimedia Appendix 2

Trial Protocol as requested in CONSORT-EHEALTH [53].

[PDF File (Adobe PDF File), 232KB - [jmir_v15i8e153_app2.pdf](#)]

Multimedia Appendix 3

Trial information to participants as requested in CONSORT-EHEALTH [53].

[PDF File (Adobe PDF File), 115KB - [jmir_v15i8e153_app3.pdf](#)]

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Abbreviations

- AUDIT:** The Alcohol Use Disorder Identification Test
- ANOVA:** analysis of variance
- ANCOVA:** analysis of covariance
- ANU:** Australian National University
- BAI:** Beck Anxiety Inventory
- BDI-II:** Beck Depression Inventory, second edition
- CBT:** cognitive behavioral therapy
- DSM-IV:** Diagnostic and Statistical Manual of Mental Disorders, 4th edition
- DUDIT:** The Drug Use Disorder Identification Test
- EQ-5D:** EuroQol Group 5-Dimension Self-Report Questionnaire
- EQ Index:** index score of the EQ-5D

EQ VAS: visual analog scale of the EQ-5D
GP: general practitioner
HADS: Hospital Anxiety and Depression Scale
ICD-10: International Classification of Diseases, 10th edition
ITT: intention-to-treat
SWLS: Satisfaction with Life Scale

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Paper III

Original Paper

Patients' Experiences of Helpfulness in Guided Internet-Based Treatment for Depression: Qualitative Study of Integrated Therapeutic Dimensions

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Abstract

Background: Quantitative research on Internet-based cognitive behavioral therapy (ICBT) has collected substantial evidence for the effectiveness of this treatment approach on health outcomes. Less is known about how patients find ICBT to be generally meaningful and helpful for treating depression.

Objective: To explore patients' experiences of being in ICBT treatment with a focus on the treatment dimensions that they considered helpful.

Methods: Choosing a phenomenological-hermeneutical approach, 14 patients were interviewed with semistructured qualitative interviews to elicit their understanding of using ICBT. The patients took part in a clinical trial using ICBT with MoodGYM, which also featured brief consultations with a clinical psychologist. The interviews were transcribed and analyzed according to the chosen methodology and organized into significant themes.

Results: The phenomenological-hermeneutical analysis identified 5 themes relating overall to the meaning of this mode of treatment in terms of helpfulness. Two related to treatment in general: (1) taking action to address one's problems and (2) the value of talking to a professional. The next two themes specifically addressed guided self-help using the MoodGYM program: (3) acquiring relevant knowledge, and (4) restructuring the new knowledge acquired through ICBT. A fifth theme concerned (5) actual changes in patients' perceptions and interactions, related to either the self-help material or the face-to-face consultations with the therapist.

Conclusions: Three important dimensions were made explicit: the active engagement of the patient, the guidance of the therapist, and the content of the treatment program. The findings pointed to (1) the role of MoodGYM as a source of new knowledge providing patients with a structured approach to work with their depression, (2) the patient's role as the primary agent of change through adapting relevant knowledge from MoodGYM to their situation, and (3) the dialogue with the therapist as a trusting relationship in which to share thoughts and feelings, receive feedback and advice, and to assist the patient in making use of the MoodGYM content.

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KEYWORDS

Internet-based cognitive behavioral therapy; ICBT; guided self-help; depression; qualitative

Introduction

Research has yielded promising results on the effects of Internet-based cognitive behavioral therapy (ICBT) on a range of mental health problems, including depression [1-3]. This form of therapy has the advantage of increased availability and at the same time puts less strain on therapeutic resources [4]. ICBT can be unguided, meaning that the patient works alone with the self-help material; or it can be guided, meaning that the patient enjoys some support and guidance from a therapist. The research on ICBT and other computerized treatments to date indicates that guided self-help and traditional face-to-face-therapy may offer roughly the same success rates for health outcomes [5], but it points to the importance of providing users with support during self-help programs [2,3,6]. Still, the role of support is not well understood in terms of the amount necessary or what it should offer [7,8].

The mechanisms through which ICBT is effective in reducing depression remain unclear. Both specific and common factors of treatment may serve as active ingredients [9]. Cognitive behavioral therapy (CBT) aims to alter the maladaptive structures and processes fundamental to depression [10], by making use of both cognitive and behavioral strategies. A key assumption in CBT is that the depressive patient can use CBT to modify or deactivate his/her depressogenic schema or develop compensatory skills. A qualitative study has provided support for the notion of compensatory skills in face-to-face CBT, where patients utilize the extensive self-therapeutic activities in CBT to manage their depression [11]. Self-therapeutic activity may involve the use of specific CBT techniques or personalized adaptations. Further, the patient might understand and cope with his/her depressive symptoms in light of new psychological knowledge. Similarly, self-therapeutic activity aimed at reducing negative cognitions may be one active ingredient in ICBT. Another line of psychotherapy research has shed light on contextual factors contributing to treatment outcome. The contextual model of psychotherapy [12] recognizes the contributions and interdependencies of other elements beyond the “bare-bones” treatment models and techniques (eg, mechanisms proposed by cognitive theory). These other factors include the actual patient and his/her expectations, factors outside the therapy situation (extra-therapeutic factors), and the working alliance between therapist and patient. The term working alliance refers to the partnership emerging between the therapist and patient in order to achieve the patient’s goal [13]. A robust relationship has been found between the quality of the working alliance—which depends on both therapist and patient factors—and outcome of treatment [14].

Although the effectiveness of computerized and Internet-based CBT is established, there is little agreement concerning the core content [15] and therapeutic process in self-help treatments [16]. Research on possible mechanisms of change has been emerging [9,16], and there is a need for studies aiming at furthering our understanding of active ingredients and processes at work in ICBT. Change in treatment specific factors for ICBT for depression, such as dysfunctional attitudes, worrying, and perceived control, has been found to mediate outcome [17]. Studies of the working alliance in Internet treatments report

overall high ratings that are within the range of alliance ratings in face-to-face therapy [18]. Qualitative research on unguided ICBT has identified both CBT-related and patient aspects as influencing depression. Issues such as computer and Internet skills and the patient’s need for emotional support were reported as important influences during ICBT [6]. Qualitative research into guided ICBT yielded similar findings. It seems that the way patients work with CBT relates to the success of their outcome and their opinion about the therapy: an active, hands-on, self-reliant approach correlates with successful outcomes and favorable opinions. The opposite case is a passive style of working that does not put new knowledge into practice, skips parts of the course material, and is in need of more support [19]. It is not clear, however, what lies behind such differences in approach or whether the cause might be low expectations to the treatment, or because the patient feels a lack of helpfulness during the ICBT process. Purves and Dutton [16] explored patients’ experiences of the therapeutic process in an unguided computerized CBT program and identified four themes in interviews with patients. These included a meaningful relationship with the self-help material, using the self-help material to create structure to their psychological state, being stimulated by the self-help material creating engagement, and an increased sense of personal agency. In sum, the current literature implies that specific and common factors contribute to the outcome of ICBT. In order to improve effectiveness and acceptability of such treatment packages, further examination of these issues are warranted [9].

This study explores patients’ experiences of helpfulness in guided Internet-based cognitive behavioral therapy for depression. We intend to combine a pragmatic intention with a phenomenological-hermeneutical approach on patient experiences rather than on isolated patient factors. Such an approach, inspired by Husserl, focuses on human experience in everyday life, explores a natural attitude, and understands the whole of an experience [20]. Further, human beings have intentional relationships with their surroundings and things in their everyday lives, that is, relationships that are experienced as meaningful. In this case, we mean to elucidate how patients experience and give meaning to the phenomenon of ICBT in an everyday context. Such experience can be narrated and presented as text, which again calls for a hermeneutical interpretation [21]. To grasp the essential meaning of ICBT, this study aims to explore the experiences of patients in an ICBT intervention with therapist support. Knowledge about what patients experience as most helpful, and how patients understand and implement the principles of CBT, is essential if we want to improve the quality of ICBT programs and patient support. The current study aims to explore patients’ experiences with ICBT, focusing especially on those aspects of the therapy that they consider most helpful.

Methods

Design

This qualitative study was conducted in parallel with a randomized controlled trial (RCT; ACTRN12610000257066). The aim of the RCT was to test a treatment approach with ICBT

that could be feasible in general practice. It compares Internet-based cognitive behavioral therapy interspersed with brief personal sessions with a therapist to a waiting list control sample. Participants in the RCT were recruited for this qualitative study when ending treatment. The first and second authors of this paper took part in the planning of the RCT and conducted the interviews. The first author worked as a therapist in the RCT but did not interview her own patients. Both the first and the second author conducting the interviews were blind to the outcome of the patients at the time of the interviews.

Description of the Randomized Controlled Trial and Treatment

Patients included in the RCT after an initial assessment had a session with their therapist who introduced the self-help program. The introduction focused on giving brief information about the theoretical basis and the empirical support, as well as the content of the program and expected work load. Patients were asked to complete the five modules of MoodGYM in sequence, one per week. They were then followed up with weekly, face-to-face consultations with the therapist over a minimum of 7 weeks. A full course treatment included eight consultations. However, the treatment protocol was quite flexible and allowed for delays in the treatment, and it did not have a maximum limit for therapist sessions. In case of delays, the therapist contacted the patients to reschedule a new appointment.

The consultations each lasted approximately 15-30 minutes, similar to the time available in general practice. The guideline script comprised three compulsory subjects: (1) symptom monitoring, (2) discussion of the topic of the last module in MoodGYM, and (3) introducing the next module and discuss patient motivation. If time permitted, other issues that patients perceived as important to their depression were also discussed.

The self-help program used in the randomized controlled trial was MoodGYM. Its aim is to help patients prevent and cope with depression, based on principles of cognitive behavioral therapy [22,23]. It was developed at the Centre for Mental Health Research at Australian National University, and its effectiveness is empirically supported [24,25]. MoodGYM has five modules containing texts explaining the basic principles of CBT, a variety of self-tests and self-help exercises, and homework in which the patient is invited to analyze some personal experience in accordance with the principles of the program. Although some of the content in MoodGYM is generic CBT, there are also some specific sections devoted to parental

relationships, relationship break-ups, problem solving, and even relaxation.

In the RCT sample, 72.6% were female, and age ranged from 18-63 with a mean of 36.1. The number of treatment sessions ranged from 1-12, with a median of 8 sessions; 40.1% did not complete the treatment program. The baseline depression scores, as measured by the Beck Depression Inventory (BDI-II) [26], had a mean of 21.7. A full description of the sample can be obtained in the forthcoming paper presenting the results of the RCT (personal communication by Høifødt, Ragnhild, March 2013).

Recruitment to the Interviews and Procedure

Overall, the study was planned to provide complementary knowledge production on ICBT different from the kind of knowledge obtained in an RCT, hence the use of a qualitative approach. The recruitment of patients to the interviews was parallel to the randomized controlled trial, with patients receiving oral and written information about our qualitative study and an invitation to participate at their final consultation. Recruitment was continuous until the desired total of 14 interviews was reached. The recruitment procedure was strategic in the sense that we aimed to include men and women, younger and older, completers and noncompleters. The therapist would provide the interviewer with contact details for consenting patients. Patients could choose the location, either at their home or at the university in comfortable everyday like settings. All patients preferred to be interviewed at the university. The interviews lasted for approximately 60 minutes, were recorded using a digital voice recorder, transcribed verbatim by the second author or a clerical assistant, and then coded using NVIVO software. The initial coding procedure comprised a separate coding by the first, second, and last author of two interviews, and subsequently checked for consensus. During the entire process of analysis, the coding and the subsequent themes were discussed and reflected upon.

The researcher's interview guide consisted of open questions inviting the patients to narrate different aspects of their ICBT experience: their motivation during progression, any changes they made in their everyday life, and any changes they perceived in their condition. This prompted answers concerning, eg, sociality, temporality, and spatiality of one's lifeworld (the sum total of physical surroundings and everyday experiences that make up an individual's world). As a whole, the interview was performed as an open dialogue interview. Table 1 presents a list of questions within each of the topic areas.

Table 1. Main questions in the interview guide.

Topic	Questions
Changes in everyday life	What was your life like before you got depressed? What was it like during your depression? How is it like after treatment? Can you describe any changes you have made during this time? Can you recall situations where you have acted differently as a result of the treatment? Do you think people close to you will have noticed any difference?
Motivation during treatment	What made you start treatment with MoodGYM? How did you progress through treatment? Which were important elements in treatment? Did you experience any difficulties?
The treatment	What did you think of the treatment? Was there anything you liked or disliked in particular? How did you like working with the computer? How did you experience the relationship with the therapist? In what way were you able to influence the progression through the treatment? Did you need to make any practical adjustment in your everyday life?

The qualitative study from the onset employed a phenomenological-hermeneutical methodology, which basically means that we sought to elicit the way participants related to the treatment. The approach is phenomenological in the sense that it understands human experience as founded in a basic relatedness to the world though merely living it in a naïve way, with a natural attitude. This experience, however, may be expressed in narratives, actions, or reflections, showing the intentionality of a human being, and may be described scientifically. This approach is inspired by Lindseth and Norberg [21] who again rest their methodology on both Husserl, Heidegger, and Ricoeur [21,27]. Semistructured interviews were conducted to elicit empirical information about patient experiences in treatment, aiming to set aside “the taken for granted” attitude of their lived experience.

Patients

Fourteen patients were recruited from the RCT sample. The patients interviewed were 5 men and 9 women (64%), aged 22-61 years. The number of consultations ranged from 3-11. Three patients (21.4%) did not complete the treatment program. At pretreatment assessment, Beck depression inventory scores ranged from 10-28 (mean 18.27). At posttreatment assessment, 6 patients (42.8%) had not changed, 1 (7.1%) had improved, and 7 (50%) had recovered, based on criteria for clinically significant change [28].

Analysis

Carrying out a phenomenological analysis requires the researcher to reflect carefully upon the taken for granted statements of one’s informants and to approach these with an attitude of “bracketing”, that is, to examine and question openly what is being expressed [20]. Also according to Lindseth & Norberg [21], a phenomenological-hermeneutical analysis cycles through different levels of understanding of the text material. First, the interview is read to achieve a superficial understanding of what the text is all about. Second, the text is analyzed in terms of its meaning units (semantics) with a reflective approach. The semantic units are then condensed to form themes and subthemes that disclose meaning in everyday words rather than merely portraying concepts. Also, the themes develop from the material rather than from the interview topics. The identified themes are, after the second step, compared with the initial cursory understanding for validation. Third, the themes are reviewed and reflected on as a whole, and an overall understanding may be reached through critical reflection based on theoretical literature. This procedure was adhered to, but it was necessary to compare the themes not only with the naïve understanding but also with the original interview transcript. And in the third step, comprehensive understanding was achieved in light of theories about change processes in psychotherapy. In summary, the analysis involved a dynamic process moving between abstracted themes and the interview transcripts for validation [27]. During the analytical steps, essential meaningful experiences with the treatment were identified and one of them was what counted as “helpful” for the patients. The themes revealing what helpfulness consisted of might emerge as pragmatic issues (which they were), but what was experienced as helpful was also interpreted as

capturing exactly how the treatment became meaningful to the patients.

Results

During analysis, several meaningful themes were identified from the interviews. The overall topic chosen for this paper is how patients perceive the treatment as being helpful. Another paper focuses on motivational aspects of the treatment (personal communication by Wilhelmsen, Maja, Jan. 2013).

Overall, we defined five themes reflecting perceived helpful dimensions. Two themes were related to being in treatment in general and were nonspecific to ICBT. These concerned (1) taking action to address one’s problems and (2) the value of talking to a professional. Two themes specifically addressed the patients’ experiences with the self-help program material: (3) acquiring relevant knowledge and (4) restructuring the new knowledge. A fifth theme concerned (5) the way that patients describe actual changes in perceptions and interactions with their environment that patients relate to the treatment they have undergone.

Being in Treatment

Taking Action to Address One’s Problem

In most cases, patients had been considering the pros and cons of seeking help for a long time, even for years. One typical response to taking this difficult step was the sense of relief and satisfaction that patients felt when they took action to address their problem. Some patients had not gotten very far with the process and had not experienced any improvement, while others were highly active during treatment and making deliberate changes to their lives one step at a time. In both cases, patients talked about the mere act of doing something as important:

Working with MoodGYM, the best thing about it all was that I was doing something about it. You know, coming to these sessions every week, getting to talk, starting the next chapter. You know, the things I worked with did not suffice, but I felt good working with it. I felt sort of like I was getting out from...getting back to normal. [Male (26)]

The analysis reflects the significance of moving from a state of passivity to one of activity. Patients recounted that they had felt a need to move forward that brought them to seek help. Taking action was in itself an achievement that engendered hope and brought a positive effect. The treatment might not be all they had hoped for, but patients still valued their own effort to try and improve their own situation. This theme is related to motivation in the treatment process, but it became evident in the interviews that this affected how the patients were feeling, as a meaningful event towards recovery.

Patients highlighted the easy access to the treatment as another important facilitator for taking action. The alternative for many people with depression would be referral to specialist health services, where long wait times leave patients passive. The alternative of a private clinic leaves patients worried about their financial liabilities. Our patients had low expectations about the abilities of general practitioners to deal with

depression—GPs were assumed to have little time on their hands and little knowledge of mental illness. In general, our patients were pleased to be offered a course of qualified therapy universally available online at no cost.

The Value of Talking to a Professional

There was consensus among the interviewees that the involvement of a therapist was vital in the treatment and that talking to a professional is very important to them. The level of satisfaction with the amount of contact with the therapist varied a great deal. Some patients were quite satisfied, while others came to realize that what they really wanted was conventional face-to-face therapy, not guided ICBT. For all patients, a trusting relationship with a professional was a fundamental part of the treatment:

I thought it [the relationship with the therapist] was really good! She didn't make me feel judged in any way. She was very accommodating. Almost as if she understood what I was talking about. She sometimes was ahead of me about things I was going to say, in a way. She understood very well what it was like. [Female (22)]

Patients expressed a need to talk freely about their issues and a chance to reveal things about themselves without fear of judgment. Their need for appropriate verbal communication was significant. Communication with the therapist was described as different from everyday interaction with others, and patients thought it essential to the treatment. The chance for patients to share their experiences, innermost thoughts, and feelings was something they found important:

In the first session I got to talk about it all. So...the first session was very important...the first and the second session, that was when I got to talk about the things that troubled me. So I believe...I think it was very important to be able to do that. [Male (26)]

Furthermore, the reciprocity of the relationship was emphasized: not in the sense that the therapist and the patient are equal, rather, the role of the therapist as a professional was appreciated. The importance of a dialogue was stressed, where the patient could ask questions, discuss issues with the therapist, receive trustworthy feedback, and be supported and acknowledged:

But, I have sort of looked for...what shall I say, a professional or an adult who has in some way supported me in my thoughts about all the things I do. Those things I do because I feel guilty, have to, but in reality don't need to. I would like a verbal confirmation that I'm doing enough! [Female (56)]

These aspects of the professional relationship, that is, having someone you can trust, a chance to freely express yourself, and receiving individual affirmation, were for some just as important as working with direct symptom relief or negative thought patterns. It seems that by engaging in this dialogue, these patients were reassured by the affirmation and support they received.

Internet-Based Cognitive Behavioral Therapy

One vital aspect of MoodGYM depression therapy is that patients are actively engaged; they receive homework aimed at challenging their repetitive automatic negative thoughts and cognitive distortions. The latter two themes: (3) acquiring relevant knowledge and (4) restructuring the new knowledge, describe ways in which the content of MoodGYM was experienced by patients. The extent to which patients could relate to MoodGYM varied greatly, so these responses provided insight into relevant dimensions of interacting with the program.

Acquiring Relevant Knowledge

Patients commonly describe features of the self-help material as being experienced as particularly relevant, issues presented in the program that “have to do with me”, or in contrast, issues that were irrelevant. Typically, patients were more satisfied with the standard content of CBT (eg, presenting the principles, cognitive distortions) rather than the content aimed at specific problems (eg, relationship break-ups, parental relationships). Patients could accept some parts of the content being of little relevance to them, as long as they could find other parts that they could learn from:

The first thing I came to the session and said, “this, this is huge”. It [a presentation of the basic ABC-model of CBT] was the drawing we saw early on, with situations, cognitions and feelings. I had never seen that drawing before...and if I were to draw it, feelings would never be in such a drawing. Because I've ignored feelings...So that was, well, a first...a sort of awakening. [Female (39)]

The fact that a patient could recognize something in the program content and feel its relevance was a way to feel support and recognition in a situation that otherwise was unfamiliar or hard to accept. The process of seeing relevance in the material is intertwined with the process of learning and acquiring new self-knowledge. Conversely, patients who found no relevance in the material were unlikely to learn anything. So for some respondents, the content raised awareness, reactivated once-familiar knowledge, or provided new insights; whereas for others, the feeling was that the content was not meaningful to them:

Well, so little by little, when I could only identify with the character that was not depressed, then it like became more and more...it was almost as if I felt myself getting annoyed by those modules. And I decided that this here stuff doesn't give me anything. [Female (28)]

Not all patients felt able to relate to the principles of CBT presented in MoodGYM. This was generally due to a mismatch of the program aims and what patients perceived as their most pressing problem. All our patients showed symptoms of depression, but not all of them felt depressive thoughts and ideas to be their principal problem. Some were quite clear in their mind that ICBT would not provide the answer to their difficulties, perhaps to the extent that they were unwilling or unable to relate to the MoodGYM content.

Restructuring the New Knowledge

Patients' accounts of their experiences with the program content show how they reflected on the material, adapting or processing it to suit their own perceived needs. Patients who found parts of the self-help program relevant did not necessarily accept it all uncritically, rather, they described an active process of interpreting the material. This also meant reflecting on past events, thoughts, and feelings in light of their newfound understanding:

I felt it [working with the modules] took a long time because I was sitting reading and trying to interact...interact with what I read...It was not that I struggled with the homework or with understanding what it said, but I chose to spend time on it. [Female (26)]

It was evident that the proposed approaches and techniques were not universally suitable, and some patients went to considerable lengths to restructure the content to suit their perceived needs. A table in module 2 gives an overview of distorted cognitions (Figure 1).

There were an awful lot of categories. How could I make it useful? On a daily basis, I had to merge some into larger groups and then work out, like, "Alright, now I'm making this type of mistake". It had to be restructured a bit, because I couldn't be bothered to sit and cram all of them. And I didn't need to either. [Male (33)]

The patients talked about how the program material made them more aware of their own negative thinking and that this awareness opened up for further reflections about the validity of those thoughts, and how such thoughts are incorporated in a negative cycle that also includes feelings and actions. However, not all patients were able to make adaptations of the material to fit their own needs, despite recognizing the relevance of the material. For some, bridging the gap between theoretical concepts of negative thinking and making the ideas their own, was far from easy. Sessions with the therapist helped the bridging process by enhancing patients' understanding and ideas about program content: "Indeed the conversations helped make the content of the Internet form more elastic". [Female (39)]

Actual Changes in Perceptions and Interactions

Patients described changes in both thought and behavior as essential. Some changes were clearly related to what they learned from the self-help program, eg, testing the truth value of their negative thinking or using specific techniques from the program, whereas other changes had been discussed with the therapist in the sessions and were not directly related to the self-help program. Changes in thought patterns, where patients started to question the content and validity of their depressive ideas, were a specific result of the self-help techniques:

And also in relation to the business of structuring and categorizing thoughts and mindsets, and doing a reality check on what you're thinking, related to what has happened or what you're feeling—that has been very helpful to me. What does this really mean? Where

does this come from? This has been very useful to me. [Female (39)]

The patients were describing how they came to realize that thoughts and ideas about an event are not accurate representations of reality. Moreover, they might be biased and need careful scrutiny. Questioning the validity of thoughts and ideas made room to explore other possible interpretations, and this process helped give patients more flexibility in their thinking. It showed, for example, how a bias in their mindset might be making their depression worse. Behavioral changes could follow such cognitive changes, including how patients related to events and how they discussed things with others. A technique in module 3 distinguishes observations from interpretations (Figure 2). The following quote illustrates how an exercise from MoodGYM ("The Reporter") is incorporated by one patient:

There were some things I remember, and that was when I got that far in the program, then they talked about a reporter. I've given that much thought, and that's something I'll take with me. Actually, I am an emotional person, and sometimes I get annoyed with myself...And then there was this here reporter...her name is Vold. She [a Norwegian television reporter] reports from the Middle East and Palestine, and I think she's good. And I imagined her in front of me...she's in the midst of fighting, or they are shooting, or they are fighting all around her, or at least in the background. And she's standing there trying to report accurately on what has happened. I think it's admirable. So I've had her with me in quite a few situations. [Female (61)]

Other behavioral changes served to break a negative cycle of self-recrimination, inactivity, and withdrawal. These changes could produce positive secondary benefits for the patients, including getting closer to the people around them:

I got to know her [his partner's] kids better, for instance. That's very positive. [Interviewer: "How did that happen?"] Well, I tried to make the best of it and play with them, not going into a room and hiding away all by myself. [Male (26)]

Some changes described by the patients revealed that their self-perception had tended to move in a positive direction, towards self-acceptance. This was evident from statements that revealed a more self-accepting and less self-critical attitude towards themselves:

If you have done something that you're not completely satisfied with, you should not think that you're a terrible person. That you can actually get a firm grip on it and work with it. [Female (41)]

Some of the changes patients made in their daily lives sprang out of the sessions with the therapist, but were not directly related to any of the program material. Examples might be practical solutions to problems discussed in the sessions, or specific strategies to break a negative cycle, designed specifically for the patient's own situation: "Yes, we had to find practical solutions, because it's not always that positive thinking can silence the negative." [Female (22)]

This is an illustration that patients could also experience other difficulties in their lives that needed attention. Examples are practical problems that needed to be tackled, in addition to the cognitive behavioral therapy provided in the self-help program.

Figure 1. Screenshot from module 2 in MoodGYM.

MoodGYM uses a list of typical errors developed by David Burns ("Feeling Good, the New Mood Therapy"). [Others](#) are available.

David Burns' Warped Thoughts

For each type of thinking, click the icon for examples.

WARPED THOUGHT	DEFINITION	CLICK ICONS FOR EXAMPLES
<p>ALL or NONE thinking</p> <p>none</p>	<p>Everything is perceived to be either full on or full off. If something isn't fully completed/ or right/ or perfect/ then its entirely uncompleted/ wrong/spoiled.</p>	
<p>Overgeneralization</p>	<p>One example of a mistake or error is interpreted as a pattern of mistakes, and errors.</p>	
<p>Mental Filter</p>	<p>One (negative) part of the picture is examined to the exclusion of the larger (positive) part.</p>	
<p>Disqualifying the Positive</p>	<p>Dismissing or ignoring any positive comment/ achievement/ compliment.</p>	
<p>Jumping to Conclusions</p>	<p>You think negatively about something without supporting evidence. There are two errors: Mind reading: You think without any evidence that someone is thinking negatively about you The fortune teller error: You truly believe that you know what will happen in the future, without evidence.</p>	

Figure 2. Screenshot from module 3 in MoodGYM.

← BACK NEXT →

FEELINGS
THOUGHTS
UNWARPING
DE-STRESSING
RELATIONSHIPS

PROGRESS

Taking the role of a reporter

(turning Clark Kent into Superman).

This is the first method for contesting warpy thoughts other than "Straight Talking".

Take the role of reporter (turning Clark Kent into Superman)

Consider taking the role of a reporter describing the events that you get upset by. This will allow you to step back from your deep involvement and automatic responses and allow you to distinguish observations from interpretations.

Let's go back to the broken car: Do you remember what Moody said here?

[next »](#)

[View text description](#)

Discussion

Principal Findings

The previous section has looked at what patients experienced as helpful with regards to treatment. These comprised basic dimensions as the very act of seeking help and being in a therapeutic relationship with a professional. Patients described their experiences of the specific CBT delivered by MoodGYM as a source of relevant knowledge that they adapted to their own situation and implemented in their everyday lives. Overall, the phenomenological-hermeneutical analysis gave knowledge of several experiences with ICBT concerning helpfulness but also provided a whole impression of how these experiences were related and understood. The patient identifies with and learns from MoodGYM material that stimulates them to engage in self-therapeutic activity. This process is supported through the consultations with the therapist. In addition, the relationship with the therapist had a function beyond supporting MoodGYM use, in providing an arena for sharing thoughts and feelings and receiving feedback and advice.

Regarding help-seeking, patients described that making a commitment to therapy was a great help suggesting that dimensions within the patient, not directly related to treatment content, have an influence on outcomes. Taking action to improve one's situation is a way of regaining control, referred to by previous authors as empowerment [16] or being compelled to take action [29,30]. Taking action would include making a commitment to the ICBT treatment and accepting its methodology, which again can be interpreted as an expression of the treatment relationship or the working alliance. The working alliance is shaped within the context of the therapy and represents the bond between therapist and patient, as well as a shared understanding of the work and goals of the treatment [13,31,32]. The patients were given an explanation of ICBT, and most accepted self-help therapy as a way forward with themselves being the primary agent of change. Yet there were also cases where the commitment was poor, and the patient did not accept the basic premises of ICBT or deemed the content of MoodGYM inappropriate to their needs. This resulted in poor motivation and little active engagement in the treatment. The success of the working alliance is strongly related to the success of the therapy outcome [33,34], which indicates that establishing a common understanding of the aims of the treatment is a vital key to recovery. There are findings pointing to the ability of patients to develop a meaningful relationship within a fully computerized treatment [16]. However, research findings concerning the working alliance in ICBT are inconclusive [18], and further research, particularly in relation to the type of support (face-to-face, telephone, or electronic messages) and treatment outcome is warranted.

The presence of a therapist was important in several ways. It means a trusting relationship can be developed, and patients have a channel for self-disclosure and supportive response. The need for disclosing thoughts and feelings, interaction, and feedback has been highlighted in previous studies [6,29,35], pointing to the role of the therapist in the therapeutic relationship as warm, empathic, affirming, and engaging [36]. In a previous

study, patients reported difficulties in translating computerized CBT content to their own social situation [6]. In the current study, sessions with the therapist added to the self-help program by opening up for discussion of the program content, assisting the patients in their understanding of the content. As such, the role of the therapist influenced the specific CBT dimensions. As in previous studies, some patients deemed the sessions confined and desired more conversation with a therapist to gain a deeper understanding of their problems [19,29]. Another benefit was that the therapist could step in when problems were beyond the scope of the program or tender helpful practical advice tailored to the individual. Clinicians consider a lack of these possibilities as potential drawbacks of ICBT [37]. Thus, patients and therapists value the flexibility and possibility to individually adapt the intervention in a way only human support can provide.

Acquiring new knowledge was a significant benefit from involvement in the MoodGYM program. Patients described themselves being able to relate to cases presented in the program. Patients actively sought out the parts of the program helpful to them and found ways to utilize this new knowledge. The findings show that these patients were not simply passive recipients of insights gleaned from MoodGYM, rather they were active seekers of relevant information, evaluated its validity, and adapted their new knowledge to their own personal situation. These findings are consistent with the perspective of patient involvement in psychotherapy [38] and with previous research where the self-help material stimulates new learning, making patients able to create more structure and order, and break problems down to smaller entities [6,16,19,30]. Within this perspective, the patient is an active agent, entering therapy with some ideas of what they need, selecting from therapy what they consider useful, making independent assessments of results, and integrating therapy experiences into everyday life.

Patients talked about self-therapeutic activities in terms of implementing their own adaptations of MoodGYM content and discussions with the therapist. Commonly, patients reported general insights and increased awareness of negative automatic thoughts and cognitive distortions in real life, similar to previous observations in ICBT [19] and face-to-face CBT [11]. For some patients, these insights enabled them to challenge the validity of such unruly thoughts. Changes in behavior and communication could bring secondary benefits, further strengthening the positive processes in play. Some changes were subtler, not being specifically bound to any given situation but seemed to represent a shift in self-esteem across all situations, with the patient becoming more self-accepting and less judgmental.

In light of the findings from the current qualitative study, guided ICBT with MoodGYM can be viewed as a dynamic process, in which the patient and the therapist work together within the self-help framework offered by the online treatment program.

Implications of the Study

The results of this study highlight how ICBT can be a useful treatment for depression by providing insight into everyday life experiences with this mode of treatment. This has brought forward both patient-near experiences and pragmatic solutions

to identified problems. The results specifically illustrate the dynamic interplay between the patient's lifeworld, the therapist, and the ICBT treatment program. This is important to keep in mind for the future development and implementation of guided self-help.

The collaborative nature of guided ICBT is evident from the results of this study. The patient plays an active role in the therapeutic process, and this point should be explicitly stated before and during the course of the treatment. Needless to say, individual patients have different capacities to get involved, some needing more support and encouragement than others.

The ease with which patients could adapt standard principles to suit their own situations varied a great deal. This realization should help inform continuing development of online self-help programs. In general, generic CBT modules were experienced as more relevant than modules targeting specific issues (eg, problem solving, relaxation), supporting previous findings [39]. Principles and descriptions in the program should be generic to the extent they are recognizable to the patient, yet designed to work with patients with a specific diagnosis [40], but adaptable to an everyday context. This precise diagnosis or description of the patient's problem needs to be prepared beforehand, allowing the patient to be matched to the most suitable program package [7].

Whether therapist support is provided through email, telephone calls, or face-to-face, it can be assumed to contribute to the outcome of the therapy directly and indirectly. Therapist support should offer the opportunity for a level of self-disclosure, in a nonjudgmental setting where patients can expect relevant, supportive feedback. The therapist also serves an important function to help patients understand the principles of CBT and help patients make the transformation from principle to everyday practice.

The role of the therapist was also vital when patients needed individual guidance or advice about how to deal with everyday challenges that might otherwise get in the way of treatment progress. Practical advice from a therapist, or an inspirational session with a sympathetic adult, could provide the motivation to embark on manageable, significant changes.

The findings of the present study point to the dimensions experienced as important by the patients interviewed, and the meaning of this mode of treatment in terms of moving from depression towards recovery. These findings may serve as a hint on how to continue to improve the practice of ICBT. It remains to explore what conditions in ICBT are sufficient and necessary to aid patients, and what distinguishes processes resulting in change from those ending in no change or deterioration.

Limitations

The sample of patients in this study is small, consisting of individuals who volunteered to join a randomized controlled trial and attend the interviews. Possibly they were highly motivated to participate in research, and they are in some way different from other potential candidates who chose not to be interviewed. Furthermore, recruiting noncompleters turned out to be difficult, and thus the completers are overrepresented in the sample. This is a limitation of the study. It is likely that completers and noncompleters have divergent views regarding the helpfulness of the treatment, and we recommend further research into the treatment experiences of noncompleters of ICBT. However, there were differences within the sample regarding outcome, and accordingly, the results also reflect the views of patients who did not improve.

The study examined patients' experiences with an online self-help program, incorporating occasional, brief face-to-face sessions with a therapist. By contrast, Internet-based therapy typically gives guidance through electronic messages or telephone calls. It is possible that the treatment examined in the current study has a greater resemblance to conventional psychotherapy than to Web-based self-help. Further investigation could identify other possible themes for discussion in other forms of Web-based self-help therapies.

The interviews were conducted shortly after the end of treatment, therefore it is not possible to evaluate to what extent potentially helpful elements impacted on patients' lives. It may be that patients were still "fired up" by the therapy at the time of the interview, but this does not necessarily mean they experienced any long-term improvements. Some findings suggest that patients can continue to engage in self-therapeutic CBT for as much as 3 months after ending treatment [11], but further research is needed to shed light on patient agency in CBT.

Conclusion

Elements in ICBT that are perceived as helpful represent the essence of the patients' experience with ICBT. This can be viewed from the perspective of the contextual model of psychotherapy, which highlights the dynamic and collaborative nature of Internet-based self-help. The findings of the current study pointed to MoodGYM as a source of relevant knowledge, providing a structured approach to working with depression. The role of the patient as the primary agent of change is highlighted, through his/her engagement in treatment, seeking knowledge, and employing it to the personal context. During the intervening guidance sessions, the therapist played a useful role by facilitating the understanding and explaining the relevance of the generic MoodGYM content, providing professional feedback and interpersonal support, as well as giving practical advice.

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Conflicts of Interest

None declared.

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Abbreviations

- BDI:** Beck Depression Inventory
CBT: cognitive behavioral therapy
ICBT: Internet-based cognitive behavioral therapy
RCT: randomized controlled trial

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Appendix I

Intervjuguide

Dato/sted

Alder

Sivilstatus

Generell oppfatning:

- **Fortell historien** om din depresjon og behandlingen du har vært gjennom.

Motivasjon:

-Hva fikk deg til å **delta** i Moodgym?

-Beskriv hvordan har du **gjennomført** behandlingen?

-Hvilke momenter i behandlingen var **viktigst** for deg? Hvordan påvirket dette framgangen i behandlingen?

-Hva har vært **vanskelig** og hvordan **løste** du det?

-Hva vil du si var **drivkraften** for deg i behandlingstiden?

-Kan du fortelle om noen **spesielle personer/hendelser** som har vært sentrale for deg i denne siste tiden?

-Hvilken betydning hadde **e-mailene** du fikk underveis?

Behandlingen

-Hvordan **opplevde** du behandlingen?

-Fortell om et **minne** du husker godt fra tiden du gjennomgikk Moodgym-behandlingen? Hvorfor dette minnet?

-Måtte du gjøre noen **praktiske endringer** i ditt hverdagsliv for å gjennomføre behandlingen?

-Hvordan tror du noen som er **deg nær** oppfattet behandlingen?

-Hvis du fikk være med å **vidreutvikle** Moodgym etter erfaringene du har gjort deg, hva ville du forandre, ta bort eller legge til?

-Hvordan opplevde du kontakten du fikk med **din terapeut**?

-Hadde du mulighet til å **påvirke** behandlingsopplegget? På hvilken måte?

-Kan du fortelle om noe du **liker** spesielt med denne måten å behandle depresjon på?

-Hvis du skulle anbefale dette **til en venn**, hva ville du framheve?

Endringer i livet:

-Kan du beskrive noen **endringer** i livet ditt som har oppstått i denne perioden?

- Kan du huske en konkret episode som du tror du **taklet annerledes** som et resultat av behandlingen?
- Kan du fortelle om noe du **gjør mindre eller mer** av etter gjennomgått behandling?
- Ville du **beskrive deg selv** på en annen måte i dag enn før påbegynt behandling?
- Hvis vi **spurte din nærmeste**, for eksempel din mann/kone, hva tror du han eller hun ville beskrive som endret i ditt liv etter gjennomgått behandling?

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 😊

Interview protocol

Date/place

Age

Relationship status

General opinion

-Can you tell me the story of your depression and the treatment you have been through?

Motivation

-What made you participate in MoodGYM?

-Describe how you went through with the treatment.

-What was most important to you in treatment? How did this influence the progress in treatment?

-What has been difficult, and how did you solve this?

-What would you say was the driving force to you during treatment?

-Can you tell me about any particular persons/events that have been important to you during this time?

-What importance did the e-mails you received have?

The treatment

-How was your experience with the treatment?

-Can you recount a memory that you remember well from the time you underwent treatment with MoodGYM? Why this memory?

-Did you have to make any practical changes in your everyday life in order to undergo treatment?

-How do you think a person close to you would perceive treatment?

-If you could contribute to develop further MoodGYM, what would you change, remove or add to it?

-How did you experience the contact with the therapist?

-Was it possible for you to influence the treatment? In what way?

-Is there anything in particular that you like about this way of treating depression?

-If you were to recommend it to a friend, what would you emphasize?

Changes in life:

-Can you describe any changes that has happened in your life during this time?

-Can you remember an event that you dealt with differently as a result of treatment?

-Is there anything that you do less or more of after treatment?

- Would you describe yourself differently today than before treatment?

- If we asked your closest family members, e.g. husband/wife, what do you think he or she would note as changed after treatment?

In closure

-Did you think of anything that you would like to add?

-Is there anything that I did not ask about that you would like to tell me?

Thank you ☺