eBehandling

Health and Work Utility, Use and User Experience of a New Digital Transdiagnostic Work-Focused Intervention for Patients in Specialist Mental Health Care

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eBehandling – Health and Work

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Protocol

Research group

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Content

Background and status of knowledge

"Twelve billion working days are lost every year to depression and anxiety alone".

(WHO 2024)

Mental health problems and disorders affect one in every five amongst the working-age adults in the OECD countries (Kessler et al 2005). And as many as two thirds of new disability pensions are due to poor mental health (OECD 2016). This constitutes a major public health challenge that also has large implications for work participation and productivity. People with mental health conditions are more often unemployed, more often in need of sick-leave and are absent for longer durations (OECD 2020). People with mental disorders report a 30% lower employment rate than those with no mental disorders (OECD 2021). Of employees reporting mental disorders, half had days away from work, compared to under a third of people without mental ill-health. As many as two thirds of new disability pensions are due to poor mental health (OECD 2016). Mental health issues are also the largest cause of disability pensioning for adults from 25 - 39 years (Brage & Thune, 2020). Mental disorders as a cause of sick-leave and disability pension have increased in the OECD countries and Norway. Major depression and anxiety are the most prevalent of the mental disorders and are therefore named common mental disorders (CMD). CMD have become a major cause of work absenteeism, with 30% of all sick leave in Norway being due to CMDs in 2024, which is an increase from 20% in 2019 (NAV 2024; Gundersen & Medalen, 2019).

The option for paid sick-leave is an important tool and an effective way to stop deterioration when used correctly. However, long-term sick leave can also have adverse consequences (Folkehelseinstituttet, 2015). This seems especially relevant for people with mental disorders due to the adverse effects of absenteeism on mental health and negative

effects on workplace relationships due to the stigma associated with mental disorders (OECD 2016; Gundersen & Medalen).

While mental disorders are a major cause of prolonged sick leave (NAV 2020), return to work (RTW) has been shown to be positively associated with improved health, especially mental health (Folkehelseinstituttet 2015). Early interventions addressing psychological aspects and vocational challenges related to work have shown a positive effect on RTW (OECD 2014). Therefore, finding ways to increase availability and reduce barriers to evidence-based treatments seems a viable route to reducing mental health's impact on sick leave and absenteeism. It may be needed to give people on sick-leave not only treatment for their mental health symptoms, but also interventions that facilitate a planned return to work as an integrated part of the treatment process.

Treatment for people with common mental disorders on sick leave

Although a reduction in symptoms of CMD seems positive for RTW the results are not straight forward. Findings from Cullen et al. (2012) show that improvement in symptoms from ordinary psychotherapy has little impact on sick-leave. The same results have been found for internet-based cognitive therapy (ICBT) by Udd-Granat et al (2023). One of the challenges in specialised mental health care is that the work focus has been an additive or extended part of the treatment, not integrated in the treatment itself. This is not in line with the recommendations for work-focused therapy (Slater et al., 2023) and might be the cause of the low impact on sick leave.

There thus seems to be a need for a focus on RTW within therapy. Several studies have been conducted on psychological treatments that specifically target return to work for people with CMDs. Systematic reviews have shown that work-focused therapy (W-CBT) has a small, but significant effect over treatment as usual on return to work (Mikkelsen & Rosholm 2018; Slater et al. 2023). Mikkelsen & Rosholm (2018) finds that 20% more

workers in the intervention groups had returned to work, compared to control groups. There is also evidence that some of the components in work-focused therapy are more important than others, namely: work related goal setting, work related psychoeducation, work-related behavioural activation with a gradual return to work plan, work related problem solving, work-related cognitive therapy and homework. (Mikkelsen & Rosholm 2018; Slater et al. 2023). Work-focused therapy, incorporating several of these efficacious components, has been studied in a Norwegian setting with good results on RTW (Reme et al. 2015; Gjengedal, et al. 2020).

Internet-delivered treatment for people on sick leave

Another challenge for traditional psychotherapy is that access to treatment for CMD is lower than the demand (OECD 2016) and the treatment available varies greatly based on country of residence and if one is situated in an urban or rural area (Barbato, et al. 2016). Internet-delivered Cognitive Behavioural Therapy (ICBT) has the potential to increase accessibility to evidence-based treatment through increased availability and flexibility, while lowering cost and reducing need for travel for the patient. It has also been estimated that ICBT is cost-effective over traditional CBT mainly due to reduction in waiting time, which reduces time spent in an untreated state that may otherwise worsen the course of the illness (Baumann, et al., 2020; OECD 2016; Standal et al. 2021). Internet-delivered treatments have shown their effectiveness across several mental disorders, both with diagnosis-specific and transdiagnostic protocols (Etzelmueller et al. 2020, Taylor et al. 2021, Hedman-Lagerlöf et al. 2023). However, the impact of traditional symptom-focused treatment on sick-leave is suboptimal and in line with findings for traditional psychotherapy (Cullen et al. 2012; Cederberg et al. 2022; Udd-Granat et al. 2023). There is therefore a need for treatment

programs with an explicit focus on RTW using the efficacious components of work-focused therapy.

A further consideration is how to accommodate for the heterogeneity when the inclusion criteria is sick-leave. A transdiagnostic approach can be better suited for heterogeneous patient groups, as it targets common vulnerability factors rather than diagnosis-specific symptom clusters (Dalgleish et al. 2020).

Work-focused therapy in a digital format

We identified three studies explicitly using W-CBT via an iCBT platform addressing work related stressors, for people on sick leave or in danger of absenteeism. These have used self-referrals and participants are recruited from a non-clinical setting, with mild to moderate symptoms. Two of these studies have focused on mental stress and its reduction to decrease or prevent absenteeism (Asplund et al. 2019, Persson et al., 2023). One also addressed the treatment of depression (Geraedts et al. 2014). Of the trials identified Persson et al. (2023) found a significant effect on work ability and short-term sickness absence using W-iCBT for stress. However, to the best of our knowledge no studies have investigated the effects of W-CBT in a digital format aimed at CMD where the population is in an out-patient clinic setting. Nor have we found a study using a transdiagnostic approach to W-iCBT.

Summary of knowledge

The evidence that W-CBT delivered face-to-face improves return to work over CBT or treatment as usual on CMD seems strong (Mikkelsen & Rosholm 2018; Slater et al., 2023). There is growing evidence that CMDs can be effectively targeted using transdiagnostic models both face-to face (Sakiris & Berle, 2019; Schaeuffele et al., 2021) and via ICBT (Dear, Staples et al. 2015, Titov, Dear et al. 2015, González-Robles, Díaz-García et al. 2020, Schaeuffele, Homeyer et al. 2020). It also seems that the perceived level of self-efficacy towards return to work can be a good predictor for reduction in work absenteeism (Gjengedal

et al. 2021). The length of absenteeism predicts an increased risk of not returning to work (OECD, 2003; Blank et al., 2008; Roelen et al., 2012; OECD, 2021). There is some evidence that baseline treatment credibility is a predictor for both dropout, adherence and outcome in ICBT (El Alaoui et al., 2015; Alfonsson et al., 2016) and that treatment adherence predicts outcome (El Alaoui et al., 2015; Hedman et al. 2015).

Knowledge gap

Current treatment is often targeting specific disorders without explicitly addressing RTW challenges and the coping strategies needed for RTW in the treatment packages. There is a need for studies that examine the potential contribution of interventions that integrate a systematic focus on work-related issues in a comprehensive therapeutic framework.

To the best of our knowledge there has been little or no research on a transdiagnostic cognitive behavioural therapy approach to work-focused therapy, nor a digital version of work-focused therapy for CMD targeting out-patients. The individual evidence of transdiagnostic ICBT and face-to-face W-CBT is compelling. An effective combination of these would be an important development towards increased availability of work-focused therapy. A small feasibility study on the program “eBehandling - Health and Work” performed by the authors have shown that the combination seems feasible, but there is a need for a larger scale study to determine the utility and use of the program for wider implementation. The potential contribution of this study is to explore the utility and feasibility of a broadly applicable treatment program for emotional disorders, that is built around RTW. There is also a need for more knowledge about the potential negative effects, as these have earlier not been adequately assessed in treatment research.

The single arm trial design aims to obtain preliminary results on treatment effects on RTW and clinical symptoms, as well as data on use and utility of the ICBT program as experienced by the patients. It is also the case that relatively little is known about what works

and for whom in the field of work-focused ICBT. This study aims to address this knowledge gap by exploring how common clinical and demographic factors impact treatment response.

Study aims

The main aim of the current study is to investigate the utility and use of a digital transdiagnostic work-focused CBT treatment program for patients with common mental health disorders on sick leave or work assessment allowance. This includes the user experience of participation and experienced utility of the treatment program. Secondary aims are related to mediators and moderators of treatment efficacy and the participants' experience with the program.

Research questions

1. To what extent does the treatment program impact Return to Work, self-reported symptoms, and everyday functioning?
2. To what extent do clinical, work-related and demographic factors affect treatment adherence and treatment response?
3. To what extent do adherence and changes in work-related self-efficacy predict outcomes?
4. What type and frequency of negative effects does participants report?
5. How do participants describe their experience of use and utility of the program, as well as its challenges and benefits?

Hypotheses of main effects

H1a. We expect a large main effect of treatment on total percentage sick leave from pre- to post treatment, with gains maintained at follow up.

H1b. We expect a large main effect of treatment on the number of participants with full return to work from pre- to post treatment, with gains maintained at follow up.

H2. We expect a large main effect of treatment on reduction on symptoms of depression and anxiety.

H3. We expect a positive main effect of treatment on Return to Work Self-Efficacy, from pre to post treatment, and sustained through follow up.

Hypotheses of moderating and mediating effects and predictors of outcome

H4. We expect a negative relationship between duration of baseline work absenteeism and degree of return to work at post. Baseline work absenteeism will moderate the relationship between treatment and return to work.

H5a. We expect treatment credibility at baseline to be predictive of treatment adherence.

H5b. We expect that treatment adherence will be a mediator between treatment credibility and treatment outcome.

H6. We expect changes on the Return to Work Self-Efficacy Scale to predict the degree of absenteeism post treatment.

H7. We expect change on the Return to Work Self-Efficacy Scale to be a mediator between baseline absenteeism and return to work post-treatment.

H8. We expect higher depression scores (PHQ-9/CORE-OM score) to be a moderator between treatment credibility and treatment outcome and adherence.

H9. We expect that fewer than 10% of participants experience negative effects caused by participation, as measured by the Negative Effects Questionnaire (NEQ).

Methods and procedures

Design

This study is a non-randomized, single arm, multi-center mixed methods clinical trial in a naturalistic setting (see Figure 1 for an overview of the study design). Participants are recruited in a real life setting in Norwegian specialised mental health care. After recruitment participants fill out questionnaires pre, interim and post treatment, in addition to follow up at 6 and 12 months after completing treatment. Interim measures are collected after six weeks. After the treatment intervention, some participants are invited to an in-depth qualitative interview.

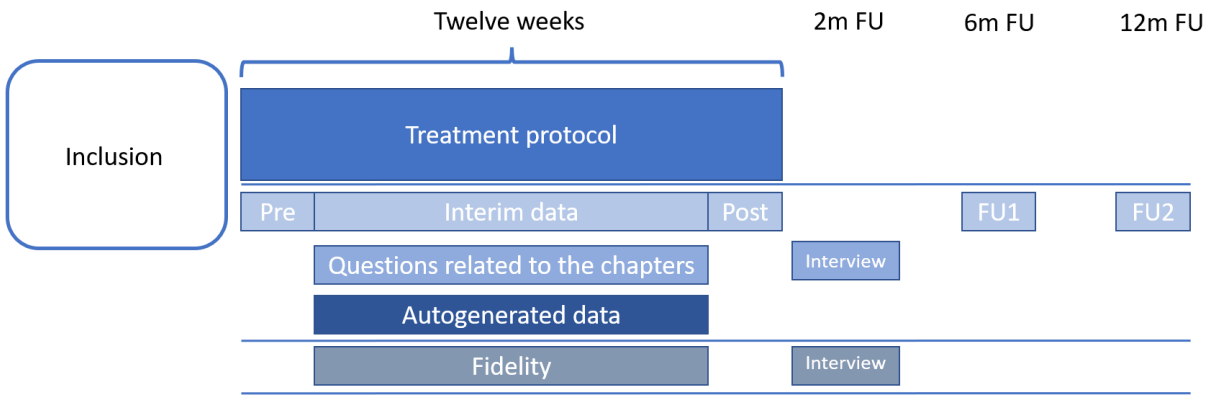

Figure 1. Study design.

Sample

Inclusion criteria for the sample are 1) being an outpatient in specialised mental health care service, 2) above 18 years old, 3) full or graded sick leave, or on work assessment allowance 4) primary diagnosis of F30 – F40 (ICD-10), 5) currently employed.

Exclusion criteria are 1) ongoing psychotic disorder and/or mania, 2) ongoing substance abuse, incl. sedative medications, 3) ongoing episode of major depression, 4) organic brain disease, 5) severe reading and writing difficulties.

Measures

Demographic variables. Self-reported data will be collected on gender, age, level of education, length and degree of sick leave, length of mental health problems and marital status. Primary and secondary F-diagnosis (ICD-10) will be reported by the eTherapist.

Questionnaires. *Primary outcome measures:* The reduction in the degree of sick leave is one of our primary outcomes and will be measured through self-report. The first question is: "are you currently on sick-leave?". The second question is activated if there is a positive answer to the first: " To what degree are you currently on sick-leave?". The answer is given on a 0-100 scale with 5 point increments.

The Return to Work Self-Efficacy Scale (RTWSE-11; (Lagerveld et al. 2010, Gjengedal et al. 2021) is an 11-item questionnaire measuring an individual's confidence in their ability to work and perform work tasks. Items are scored on a scale from 1 ("Totally disagree") to 6 ("Totally agree"). Items 2 and 6 are reversed. Total scores of 3.7 or below are associated with less probability of returning to work, while scores of 4.6 and above are associated with increased probability of returning to work (Gjengedal et al. 2021).

Secondary outcome measures: The Generalized Anxiety Disorder-7 (GAD-7; (Spitzer et al. 2006) is a measure of worry and anxiety and consists of seven items scored from 0 ("Not at all") to 3 ("Nearly every day") and one additional item measuring how the symptoms affect functioning. The Patient Health Questionnaire-9 (PHQ-9; (Kroenke, Spitzer & Williams 2001) measures depression severity. The measure consists of nine items scored from 0 ("Not at all") to 3 ("Nearly every day"). The Work and Social Adjustment Scale (WSAS; (Mundt et al. 2002) measures impairment in functioning. The measure consists of five items scored from 0 (not at all impaired) to 8 (very severely impaired). CORE-OM (Evans et al. 2002) is a 34-item self-report, measuring well-being, symptoms, elements of risk, and function on a five-point scale ranging from "not at all" to "most, or all the time". CORE-10 (Barkham et al. 2013) is a ten item self-report measuring symptoms, well-being, functioning and risk on a five-point scale ranging from "not at all" to "most, or all the time". The Negative Effects Questionnaire (NEQ) (Rozental et al. 2016, Rozental et al. 2019) is a 20-item questionnaire evaluating adverse or unwanted events during treatment. Participants report whether a specific event occurred during treatment ("Yes"/"No") and then indicate how negatively they were affected by it on a scale ranging from 0-4. An adapted version of the Credibility Rating Scale (Borkovec & Nau 1972) will be used to assess treatment credibility. The scale consists of five items where participants rate their credibility/expectancy-for-improvement on a 10-point scale.

System data on user behaviour. Data on use and user behaviour will be extracted from the system and combined with data from the self-report questionnaires collected. Information about the actual program use will be generated by the e-health platform Youwell. The data includes the extent to which participants complete the treatment, where and when they drop out, and how long they need to complete individual parts. Further we will look into whether there are areas in the treatment that require more time than others, which elements are used

most and least frequently, and how the therapist guidance is used. Further we also will analyse how long each session lasts and what system and platform they use. Each eBehandling location will also maintain local statistics on the number of assessment interviews, participants included and excluded to assess acceptance in the patient population and hospital setting. This data collection will be recorded by on-site super users. Efforts will be taken to ensure that this registration is implemented in the Youwell platform.

Qualitative in-depth interviews. Two months after completion of the program, a subset of participants will be invited to an in-depth interview (See Appendix A for the complete Interview Guide). We will use purposive sampling to select participants who represent a diverse range of demographics (age, gender) and outcomes (treatment responders and non-responders). Care will be taken to include participants from different treatment sites. We aim to recruit a total of 20 participants for the qualitative interviews, likely ensuring richly-textured information on a broad array of participant experiences.

The interview has a semi-structured design with six questions and related probes (See Appendix A for the complete Interview Guide). The interviews will be conducted by research fellow Henning Monsen. The interviews will focus on the participants' experience of the feasibility of the intervention, including aspects of the treatment viewed as helpful and less helpful. All interviews will be audio recorded and transcribed verbatim.

Intervention

The treatment intervention is a digital transdiagnostic work-focused cognitive behaviour therapy program. The program consists of seven modules (See Table 1 for an overview, and Appendix B for an in-depth review of the modules) consisting of psychoeducational texts, imagery and models, in addition to therapist-tailored tasks for the

participants. The treatment model is based on traditional CBT principles and adjusted to target transdiagnostic maintaining mechanisms in anxiety and depression such as frequent negative emotions and aversive reactions to these that leads to various forms of avoidant coping that serve to reinforce the negative emotional cycle.

Table 1.

The modules of the digital program eBehandling – Health and Work

Module 1	Introduction to the program
Module 2	Where can I get help? How can I support myself?
[1]Module 3	Self-help through constructive and supporting thoughts
Module 4	Helpful actions
Module 5	Working with/through the body
Module 6	Emotions
Module 7	Put it all together and relapse prevention

Treatment will be given by trained eTherapists with specific training in the eBehandling - health and work protocol. They will be given a two-day certified course in work-focused therapy delivered by the National Centre of Competence at Vinderen DPS. Further they will be given a one-day introduction on the use of W-CBT within a digital format by the authors of the program. Further supervision will be facilitated by the research fellow. Adherence and fidelity will be measured through reading eTherapist-participant correspondence and will be rated by the main author of the treatment protocol (Peter Prescott) and the main author of the Norwegian translation of W-CBT, Torkil Berge.

Statistical analyses

Quantitative analyses. In order to identify factors associated with treatment success and outcomes, hierarchical linear mixed modelling analyses (HLM, "multilevel") will be conducted. In longitudinal HLM, measurement occasions (time) are nested within participants. Fixed effects are average (main) effects, and do not vary across subjects. Random effects vary across subjects and/or measurement occasions (e.g., a random intercept model vs a random intercept, random slope model). In these models, data may be missing at random and at different occasions for different subjects (Tasca & Gallop 2009). The models will be checked if they fulfil the model assumptions of normality of residuals, linearity and homoscedasticity. The dependent variables are sick leave, work related self-efficacy (as measured by RTWSE-11), depression severity (PHQ-9), anxiety (GAD-7), well-being, symptoms, risk and function (CORE-OM) and impairment in functioning (WSAS). The predictors are: Treatment (time), duration of sick-leave prior to treatment, treatment credibility, work related self-efficacy, depression severity and adherence. Comparisons are modelled through main effect and interaction effect analysis (e.g. Time x "Baseline work absenteeism" interaction). Predictors will be centred using grand mean centering. T-values and degrees of freedom will be estimated using "Sattertwaite" correction (Luke 2017). The effects sizes will be converted from *t*-values and degrees of freedom to Cohen's *d* using the R-package "effectsize". Estimating indirect effects (mediation), we will apply "causal mediation analysis" (CMA), that is a method to split a total effect of an independent predictor (X) into a direct (C) and indirect effect (M). The indirect effect is transmitted through a mediator to the outcome. CMA will be conducted under the assumption of sequential ignorability. The X will be measured at baseline, the M at intermediate treatment, and the outcome(s) at post-treatment (Zhang et al. 2016). See Figure 2 below for a tentative model.

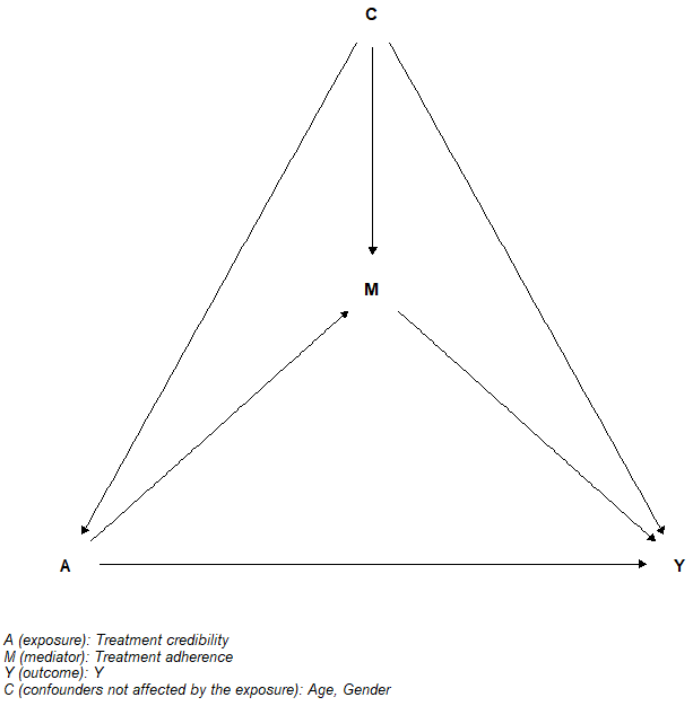

Figure 2. Model of mediation.

Corrections for multiple analyses will be done by using Jaccard`s correction (Jaccard, 1998) to decrease risk of Type I error when applying several statistical tests.

Qualitative analyses. Transcribed interviews will be analysed with the software NVivo 14 using reflexive thematic analysis (Braun & Clarke 2006, Binder, Holgersen & Moltu 2012, Braun & Clarke 2019). By comparing the individual accounts, we want to identify both patterns of commonalities and differences in participants' experiences and formulate these as themes. This phenomenological and interpretive qualitative approach can serve to explore experiences of self in contexts, interpretations of events, narrative structuring and meaning making processes closely, providing important descriptions of patient experiences that may contribute to detect challenges with the treatment protocol and improve the future delivery of the intervention. We have not set a prior hypothesis for the qualitative analysis, as we wish to explore the data inductively and to formulate themes as richly as possible in accordance with

participants' responses. Care will be taken to stay close to the wording and narratives of participants, grounding our findings in their experiences rather than our preconceived notions as researchers.

Power analyses

In a multilevel model, the fixed effects are comparable to ordinary repeated t-tests, and thus, using this as a proxy model with a moderate effect size (d = 0.6), power = 0.8, alpha = 0.05, tails = "two.sided", we need 25 subjects for detecting a single main effect Murayama, Usami and Sakaki (2022); see Summary-statistics-based power analysis (shinyapps.io). But, as stated by Van Voorhis and Morgan (2007): "*if the circumstances allow, a researcher would have better power to detect a small effect size with approximately 30 participants per variable*" (page 48). Following this rule of thumb, we plan for 30 participants per predictor (unique main effects), thus a total sample size of 300 participants. Calculating a drop-out rate of 30% gives a total sample size of N = 390. Calculating power for indirect effects – or mediation – we used the following online shiny app Monte Carlo Power Analysis for Indirect Effects (shinyapps.io), published by Schoemann, Boulton and Short (2023). Using (El Alaoui et al. 2015) as a proxy study for the direction and strength of association between our variables, they found that both treatment credibility and treatment adherence were significantly predictors of faster change and lower post treatment scores in a routine psychiatric care based ICBT for social anxiety disorder. In the same study, a high level of treatment credibility was associated with higher treatment adherence. Hence, defining X = treatment credibility, M = treatment adherence and Y = treatment outcomes, we set the correlation of X-M (a-path) = 0.3 (SD = 1), X-Y (c-path) = 0.30 (SD = 1) and M-Y (b-path) = 0.30 (SD = 1) , power = 0.8, alpha= 0.05, setting random seed to "0512", using 5000 replications with 20000 Monte Carlo draws per replication, we need N = 155 to have a power of 0.80, 95% CI [0.79-0.82].

Procedure

Inclusion will be open for 18 months, planned from September 2024. Participants will be recruited from outpatient specialised mental health care facilities in the Western Norway Regional Health Authority and South-Eastern Norway Regional Health Authority. After recruitment, each participant will undergo an assessment for eligibility where inclusion and exclusion criteria are evaluated. If eligible, participants are asked to sign a written informed consent to participation before enrolment in the study. Participants will receive access to the program after consent has been given, using level four secure login, for example BankID or Buypass ID. Participants receive a short tutorial of the program by their eTherapist. When logged in the first time, and as a mandatory task before given access to the program, participants are asked to revise their consent in regards to their unidentifiable data being used in research. Participants can at any time during treatment withdraw their consent. In this case they will be able to continue treatment, but their user data will not be exported for research purposes. Demographic variables and questionnaires will be given as a mandatory task before the first module and are registered directly in the program. The program is set to take 12 weeks to finish.

The main form of contact between participant and eTherapist will be via asynchronous messages. If asked for by the participant, or evaluated as necessary by the eTherapist there will be contact via phone or face-to-face. If a participant fails to log in for more than seven days the eTherapist will make contact via phone or SMS giving them an appointment to evaluate further progress. If a patient drops out of the program the eTherapists are to use their local procedures to how this person is taken care of, see also section for Ethical Considerations.

After 12 weeks the participants will be given a concluding session face-to-face where the next step is decided: End treatment, further treatment within the specialist mental health

care services or referred to a different treatment option. Regardless of this the participants will have access to the treatment program, without therapist contact, for six months after completion.

Participants will be asked to take part in a voluntary interview with a research fellow in the project. After six and 12 months, participants will be notified via SMS asking them to fill out self-report questionnaires. They will be given two reminders via SMS if they do not respond. If they do not fill in the forms after the two reminders they will be regarded as lost to follow up.

Project management

The project has academic and clinical collaborators. For a description of implementation of the project, see the complete Project Directive for Implementation in Appendix C.

Academic collaborators

University of Bergen. Main supervisor for the PhD candidate is associate professor Jon Vøllestad and co-supervisor is Professor Helge Molde. They both have extensive experience with conducting clinical trials and supervision.

Centre for Research-based Innovation (SFI) ForHelse. Professor Tine Nordgreen, Specialist in Clinical Psychology, is head of SFI ForHelse and leads the work package related to treatment efficacy. She has an important role in the development and implementation of digital treatment interventions nationally. In this project she represents the SFI which will provide expert know-how on implementation of digital treatment programs. In addition, she will personally contribute to the design of the study and in interpreting the results as a co-author.

Diakonhjemmet Hospital dept. Vinderen. Specialist in Clinical Psychology Torkil Berge and Head of Department of Research and Innovation Ragne Gjengedal, PhD, Specialist in Clinical Psychology, are collaborators at Diakonhjemmet hospital. They both have long experience in conducting studies and special competence on work-focused therapy. Department Vinderen has a national responsibility for the dissemination of work-focused therapy and has authored the translated manual for work-focused therapy into Norwegian (Berge et al., 2019). They will continue to contribute with counselling and guidance on the development of W-CBT and in the education and guidance of eTherapists delivering the program.

Solli DPS. PhD and analyst Pål W. Wallace is project leader. Head of Research and psychologist Kristine Sirevåg is an academic collaborator involved in study design and evaluation of results. Research fellow Henning Monsen is a planned PhD candidate in the study and is key to the implementation of the project as the daily manager.

Macquarie University, Sidney, Australia / Mindspot Australia. Professor Nick Titov, Specialist in Clinical Psychology, is the Executive Director of the Australian national MindSpot Clinic, Australia's version of eBehandling. Nick will contribute to the design of the study and the evaluation of the results.

User representatives. Trine Halhjem and Sigve Moss-Knutsen are participating in the evaluation of the program and the study procedure from a user perspective, including alpha-testing and reviewing. Astrid Gytri represents the user perspective in the steering committee.

Clinical collaborators

Solli DPS. Director Frédéric Larsen is responsible for ensuring patient recruitment from Solli DPS.

Vestre Viken Hospital Trust. Monika Strand is a research consultant in the department of research and development for Vestre Viken Hospital Trust and will help coordinate the research participation at the hospital and its clinics. Nils Lagerström Breines is the head of eBehandling and will be responsible for the patient recruitment.

Østfold Hospital. Tommy A. Jørgensen is the Project Lead for Technology Supported Treatment at the Psychiatric clinic at Østfold Hospital and will ensure that the hospital recruits and treats patients.

Akershus University Hospital. Tale Øi leads the Clinic for Work focused Therapy at Groruddalen District Psychiatric Hospital and will ensure that the hospital recruits and treats patients.

Innlandet Hospital Trust. Pål Andreassen is the department head of Lillehammer District Psychiatric Hospital and will ensure that the hospital recruits and treats patients.

Diakonhjemmet Hospital. Torkil Berge is a Subject development advisor (Fagutviklingsrådgiver) at the Hospital and will recruit and treat patients.

Bjørgvin DPS. Fredrik Hiis Bergh is the Clinic Director of Bjørgvin District Psychiatric Hospital will ensure that the hospital recruits and treats patients.

Vestfold Hospital Trust. Kenneth Kvisle is the Section leader at Vestfold District Psychiatric Hospital which focuses on work-focused therapy and will ensure that the hospital recruits and treats patients.

Fonna Hospital Trust. Arne Thomas Lundquist leads the general psychiatric polyclinic at Haugaland District Psychiatric Hospital and will ensure that the hospital recruits and treats patients.

Ethical considerations

The therapist's level of competence

The therapists giving the treatment program are clinical psychologists or have at least a bachelor degree in health (Nurses, social workers and occupational therapists). In addition all therapists are trained in eTreatment in general, this program specifically and are given weekly or bi-weekly guidance on eTherapy within their workplace and by the project group.

Monitoring suicidal risk or behaviour

Participants will each week answer question 10 (suicidal ideations) of the Montgomery and Åsberg Depression Rating Scale (MADRS; Malt, 2016; Montgomery & Asberg 1979) and the total CORE-10. Both of these questionnaires have a cut-off for risk which, if surpassed, leads to an automatic text message and e-mail to the participants' eTherapist and local program supervisor. The eTherapist, or the program supervisor contacts the participant and follows their local procedure on assessing suicidal risk and take precautionary measures as deemed necessary. This will include a face-to-face evaluation and assessment of the level of care needed. The process and conclusion will be documented in the participants electronic journal (EPJ).

Transdiagnostic treatment for specific or comorbid diagnosis

There is compelling evidence that transdiagnostic treatment protocols are effective in influencing the underlying mechanisms of CMDs through the reduction of fear and avoidance of-, and increasing acceptance of emotions, physical sensations and establishing alternative, more adaptive behaviours (González-Robles et al. 2020, Schaeuffele et al. 2021). This is found in both face-to-face therapy and ICBT. As we have developed the treatment in the current study on these established principles we see no imminent increased risk of reduced effect of the treatment on CMDs in this study.

In the case of participant drop out

If a patient drops out of treatment, or together with their eTherapist concludes that the treatment program of this study is not suitable, they will be given access to other, suitable treatment either via “eBehandling” or face-to-face treatment at their local District Psychiatric Center. (DPS).

Data and privacy protection

The Youwell platform and concerns of health information have been processed and approved for clinical use via the Western Norway Regional Health Authority based on a risk and vulnerability analysis and Data Protection Impact Assessment (DPIA, See Appendix D for the DPIA). The process in regard to research within a clinical setting is started within Helse Vest and is scheduled to be finished before July 2024. Regarding the specific considerations concerning data extraction this has been evaluated together with a data protection officer (PVO) using a DPIA. Data will be extracted by the PhD candidate using a researcher's access. This grants access to all the reports on self-evaluation and program usage, bar free text answers. It does not give access to the personal profiles of the participants, nor their activities in the program. The export is further limited by default to exclude any who have withdrawn their consent during treatment. Data will be encrypted and saved on secure storage area from Helse Vest IKT and on safe storage (SAFE) at UiB.

Financing sources

The study is currently funded by Solli DPS and previously assigned strategic funding from the Western Norwegian Regional Health Authority. We will apply for funding from the Western Norwegian Regional Health Authority.

Conflicts of interest

No conflicts of interest are stated by the research project group.

Publications and communication of results

The results will be published in high impact, international open access peer review journals. The titles of the planned papers are:

Paper I: The use and utility of a new digital transdiagnostic work-focused cognitive behaviour therapy program for patients on sick leave in specialised mental health care.

Paper II: Mediators and moderators for treatment utility of a digital work-focused therapy program.

Paper III: Participants experience with digital work-focused therapy – a qualitative study.

The results will be presented at international and national conferences. The PhD candidate in the study will contribute with popular science articles for user groups and the general population. Speeches and lectures will be given to relevant groups such as health care practitioners in specialised mental health care, municipal health care practitioners and relevant user organisations.

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Despite a longstanding and widespread influence of the diagnostic approach to mental ill health, there is an emerging and growing consensus that such psychiatric nosologies may no

longer be fit for purpose in research and clinical practice. In their place, there is gathering support for a "transdiagnostic" approach that cuts across traditional diagnostic boundaries or, more radically, sets them aside altogether, to provide novel insights into how we might understand mental health difficulties. Removing the distinctions between proposed psychiatric taxa at the level of classification opens up new ways of classifying mental health problems, suggests alternative conceptualizations of the processes implicated in mental health, and provides a platform for novel ways of thinking about onset, maintenance, and clinical treatment and recovery from experiences of disabling mental distress. In this Introduction to a Special Section on Transdiagnostic Approaches to Psychopathology, we provide a narrative review of the transdiagnostic literature in order to situate the Special Section articles in context. We begin with a brief history of the diagnostic approach and outline several challenges it currently faces that arguably limit its applicability in current mental health science and practice. We then review several recent transdiagnostic approaches to classification, biopsychosocial processes, and clinical interventions, highlighting promising novel developments. Finally, we present some key challenges facing transdiagnostic science and make suggestions for a way forward. (PsycINFO Database Record (c) 2020 APA, all rights reserved).

Etzelmueller, A., et al. (2020). "Effects of Internet-Based Cognitive Behavioral Therapy in Routine Care for Adults in Treatment for Depression and Anxiety: Systematic Review and Meta-Analysis." J Med Internet Res **22**(8): e18100.

BACKGROUND: Although there is evidence for the efficacy of internet-based cognitive behavioral therapy (iCBT), the generalizability of results to routine care is limited. OBJECTIVE: This study systematically reviews effectiveness studies of guided iCBT interventions for the treatment of depression or anxiety. METHODS: The acceptability (uptake, participants' characteristics, adherence, and satisfaction), effectiveness, and negative effects (deterioration) of nonrandomized pre-post designs conducted under routine care conditions were synthesized using systematic review and meta-analytic approaches. RESULTS: A total of 19 studies including 30 groups were included in the analysis. Despite high heterogeneity, individual effect sizes of investigated studies indicate clinically relevant changes, with effect sizes ranging from Hedges' g=0.42-1.88, with a pooled effect of 1.78 for depression and 0.94 for anxiety studies. Uptake, participants' characteristics, adherence, and satisfaction indicate a moderate to high acceptability of the interventions. The average deterioration across studies was 2.9%. CONCLUSIONS: This study provides evidence supporting the acceptability and effectiveness of guided iCBT for the treatment of depression and anxiety in routine care. Given the high heterogeneity between interventions and contexts, health care providers should select interventions that have been proven in randomized controlled clinical trials. The successful application of iCBT may be an effective way of increasing health care in multiple contexts.