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Effectiveness of Prompt Mental Health Care, the Norwegian Version of Improving Access to Psychological Therapies: A Randomized Controlled Trial

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Keywords
Prompt Mental Health Care · Depression · Anxiety · Cognitive behavioral therapy · Randomized controlled trial · Improving Access to Psychological Therapies

Abstract
Background: The innovative treatment model Improving Access to Psychological Therapies (IAPT) and its Norwegian adaptation, Prompt Mental Health Care (PMHC), have been evaluated by cohort studies only. Albeit yielding promising results, the extent to which these are attributable to the treatment thus remains unsettled. ***Objective:*** To investigate the effectiveness of the PMHC treatment compared to treatment as usual (TAU) at 6-month follow-up. ***Methods:*** A randomized controlled trial with parallel assignment was performed in two PMHC sites (Sandnes and Kristiansand) and enrolled clients between November 9, 2015 and August 31, 2017. Participants were 681 adults (aged ≥18 years) considered for admission to PMHC due to anxiety and/or mild to moderate depression (Patient Health Questionnaire [PHQ-9]/Generalized Anxiety Disorder scale [GAD-7] scores above cutoff). These were randomly assigned (70:30 ratio; $n = 463$ to PMHC, $n = 218$ to TAU) with simple randomization within each site with no further constraints. The main outcomes were recovery rates and changes in symptoms of depression (PHQ-9) and anxiety (GAD-7) between baseline and follow-up. Primary outcome data were available for 73/67% in PMHC/TAU. Sensitivity analyses based on observed patterns of missingness were also conducted. Secondary outcomes were work participation, functional status, health-related quality of life, and mental well-being. ***Results:*** A reliable recovery rate of 58.5% was observed in the PMHC group and of 31.9% in the TAU group, equaling a between-group effect size of 0.61 (95% CI 0.37 to 0.85, $p < 0.001$). The differences in degree of improvement between PMHC and TAU yielded an effect size of –0.88 (95% CI –1.23 to –0.43, $p < 0.001$) for PHQ-9 and –0.60 (95% CI –0.90 to –0.30, $p < 0.001$) for GAD-7 in favor of PMHC. All sensitivity analyses pointed in the same direction, with small variations in point estimates. Findings were slightly more robust for depressive than anxiety symptoms. PMHC was also more effective than TAU in improving all secondary outcomes, except for work participation ($z = 0.415$, $p = 0.69$). ***Conclusions:*** The PMHC treatment was substantially more effective than TAU in alleviating the burden of anxiety and depression. This adaptation of IAPT is consid-

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ered a viable supplement to existing health services to increase access to effective treatment for adults who suffer from anxiety and mild to moderate depression. A potential effect on work participation needs further examination.

Introduction

Anxiety and depression are among the most common mental disorders, affecting 1 in 14 [1] and 1 in 20 [2], respectively, at any given time globally. The conditions are associated with substantial impairment in function and quality of life, resulting in vast amounts of human suffering and costs at the individual, family, and community level. In Norway, anxiety and depression are estimated to be the fourth and third most important causes of nonfatal health loss, respectively [3], largely due to their high prevalence and early adulthood onset [4]. They thus also have major consequences for work life participation [5, 6] and work functioning [7, 8].

Meanwhile, there is a huge gap between the number suffering from anxiety and depression and the number seeking and receiving minimal adequate treatment. This is the case not only in low- and middle-income countries, but also in high-income countries [8–10]. Already back in 2001, the World Health Organization advocated ten recommendations to reduce the treatment gap. Among others, treatments should be made more readily available in primary care, and training of mental health professionals should be increased [11].

Improving Access to Psychological Therapies (IAPT) is the British response to this challenge, launched by the UK Government in 2007 for the English National Health Service. In short, this large-scale initiative involved massive training of new therapists to provide stepped-care psychological treatment following the National Institute for Health and Care Excellence guidelines, with cognitive behavioral therapy (CBT) as the main treatment approach. The model was first piloted in two demonstration sites and is now widely rolled out across England [12].

Also in Norway the mental health treatment gap is estimated to be high [13], and a 2014 OECD report urged Norway to address this weakness in care provision, in particular concerning the treatment of clients with mild to moderate anxiety and depression [14]. In 2015, it was estimated that only 10% of primary mental health care full-time employees were allocated to help this group of clients. Further, in many municipalities follow-up by general practitioners (GPs) is the only publicly available service [15].

Prompt Mental Health Care (PMHC) is the Norwegian adaptation of IAPT, initiated as a pilot project in 2012 by the Norwegian Directorate of Health commissioned by the Ministry of Health. Like IAPT, PMHC represents an innovative strategy to improve access to mental health care in Norway, offering broad, quick, and low-threshold access to evidence-based treatment for anxiety and depression. The key characteristics of the PMHC's approach are that (a) clients can directly contact PMHC, while contact with standard mental health services requires a referral from a GP, (b) PMHC aims to provide access to mental health treatment within 48 h, while standard waiting lists are often up to 12 weeks, and (c) by including less therapist contact per client through focused and brief treatment and "low-intensity treatments" (such as guided self-help and group courses), more clients can receive treatment [16]. Collaboration with the GP, the Social Insurance Agency, and other relevant actors at the municipality and secondary care levels is emphasized in order to achieve an integrated treatment and rehabilitation process. The treatment offered is CBT and is anticipated to lead to reduced levels of symptoms of anxiety and depression as well as improved quality of life and work life participation.

Investment on return analyses indicate solid gains from scaling-up effective treatments for depression and anxiety; globally a 3.3–5.7 to 1 gain of economic and value of health returns is estimated [17]. A viable scale-up depends, however, on the treatments provided in fact being effective and reaching those in greatest need [18], urging proper evaluation of the outputs of these large-scale initiatives. Evaluations based on single-group pre-post design and benchmark methodology have indeed yielded promising results in both IAPT and PMHC. An initial evaluation of IAPT that was carried out between 2006 and 2007 in Doncaster and Newham indicated that both sites achieved good recovery rates (55–56%) [19, 20]. Also after the full national rollout, the program has continuously been monitored, with the latest annual report showing an average recovery rate of 50.8% [12]. The evaluation of the first 12 PMHC pilot sites that was carried out between October 2014 and December 2016 revealed comparable findings in terms of recovery rate (recovery rate comparable to IAPT based on last observation carried forward = 57%, multiple imputation-based recovery rate = 65%) [21]. The IAPT and PMHC results should, however, be interpreted with caution, as they may be prone to selection bias [22]. It is plausible that the characteristics of the clients in the IAPT/PMHC samples are not fully comparable to the benchmark samples derived from previous

Table 1. Inclusion/exclusion criteria for randomized controlled trial study participation

Requirements for services	Exclusion criteria
PHQ-9/GAD-7 scores above cutoff level Being 18 years of age or above and a resident in one of the pilot site municipalities Basic verbal and oral Norwegian proficiency	Entitled to secondary care services due to *eating disorder*, suicide risk, bipolar disorder, severe depression, *invaliding anxiety*, psychotic symptoms, severe substance abuse, personality disorder, *two or more previous treatment attempts without effect*, or *serious physical health problem as prime problem*

The italic exclusion criteria are assumed to be less frequently observed in the context of PMHC and are therefore not mentioned in the Norwegian Directorate of Health guidelines, but were added to the randomized controlled trial protocol for the sake of completeness. GAD-7, Generalized Anxiety Disorder scale; PHQ-9, Patient Health Questionnaire; PMHC, Prompt Mental Health Care.

CBT trials. The benchmarks used by Clark et al. [20] may, for example, represent more severe clinical populations as compared to the IAPT/PMHC population, which in turn may be associated with the lower natural recovery rates (5–20% [20]) observed in untreated benchmark control groups. As such, the threat of selection bias makes it difficult to infer to what extent the observed gains are attributable to the treatments provided in the respective initiatives. To counter the uncertainty from existing evaluations, we conducted a randomized controlled trial in two PMHC pilot sites (Kristiansand and Sandnes), comparing the PMHC treatment to treatment as usual (TAU). The main goal of this study was to investigate whether the PMHC treatment was more effective as compared to TAU in reducing symptoms of depression and anxiety at 6-month follow-up. Secondary outcomes were work participation, functional status, health-related quality of life, and mental well-being at 6-month follow-up.

Subjects and Methods

Study Design

Trial Design. The study was reported according to the CONSORT statement and no changes to the design were made after trial commencement. The trial has a randomized controlled superiority design with parallel assignment. The participants were randomized on a 70:30 ratio (PMHC versus usual GP care [TAU]) with simple randomization within each of the two sites with no further constraints. A computerized random number generator was used for group assignment.

Study Setting. The trial was conducted within routine care at the PMHC sites in Kristiansand and Sandnes municipalities. The National Institute of Public Health was responsible for the study design and data collection. The study was conducted in close collaboration with the local sites and municipality health services. Kristiansand and Sandnes are Norway's sixth and seventh largest towns (88,400 and 74,800 inhabitants by January 1, 2016, respectively [23]), situated in the southwest. The sites were established after a second round of grant allocation by the Norwegian Directorate of Health, including establishing grants for a 4-year period (2013–2017), with requirements of local municipality funding following the establishment phase. The sites opened for ordinary intake in the autumn of 2014 (Sandnes: September; Kristiansand: December), following a period of establishing the service, recruitment, and education of the team workers. Similar to the first 12 pilot sites and as previously described [21], both teams started with 4 full-time equivalents (4 therapists in Sandnes, 6 in Kristiansand). Each site had one clinical psychologist who carried the professional responsibility. All workers had a minimum of 3 years of relevant higher education and had completed an additional mandatory 1-year training in CBT including an IAPT-based curriculum, adjusted to the Norwegian context. All therapists had individual treatment responsibilities. In Kristiansand, 3 therapists (including the psychologist) quit during various phases of the project and were not replaced.

Participants

Eligibility for the PMHC service is based on a defined set of inclusion and exclusion criteria, which were also applied in the trial (Table 1). The main inclusion criterion was anxiety and/or mild to moderate depression (defined as Generalized Anxiety Disorder scale (GAD-7)/Patient Health Questionnaire (PHQ-9) scores above cutoff). The requirement of Norwegian language proficiency of participants was added to the trial for practical purposes, though this, according to the site personnel, resembled ordinary service.

Methods of Recruitment

Information about the trial was provided on the municipality web pages, in local newspapers, and on local radio. All GPs in the catchment areas were informed through an information letter from the National Institute of Public Health and directly by the service providers at local GP association meetings. All clients contacting PMHC in Sandnes and Kristiansand, both GP- and self-referred, got an appointment for individual assessment at the PMHC clinic. In this detailed screening and assessment, one of the therapists conducted a clinical interview with the client. The therapist identified the relevance and severity of the mental health problems, the available client resources, and motivation for treatment. The client received information about the study and the treatment methodology within PMHC. To minimize the nocebo effect, comprehensive information about the rationale for randomization was provided. The therapist then reviewed all information and decided on inclusion/exclusion in consultation with the client.

Randomization and Masking

Clients who agreed to participate were asked to register to a secure online data portal specifically developed for the evaluation of PMHC by the Norwegian Social Science Data Services. The data portal was used for administrative purposes, to randomize eligible clients, and to collect all questionnaire data from both clients and therapists. When registered, the participants filled in the baseline questionnaire. Following completion, the participants were randomized. A 70:30 ratio was used to make the PMHC program available to as many clients as possible while at the same time ensuring a control group of sufficient size. Full allocation concealment was achieved by using the web-based central allocation application that was integrated in the data portal from the Norwegian Social Science Data Services. Participants were subsequently informed about their allocation – PMHC clients by their assigned therapist and TAU clients through a standardized letter that was sent by mail by the project coordinator. Because of the nature of the intervention, participants and therapists could not be blinded to treatment.

Procedures

Interventions: PMHC. As described previously [21, 24, 25] and above, the PMHC treatment is based on the IAPT treatment model and includes both low-intensity (guided self-help, psychoeducational courses) and high-intensity (individual treatment) treatment forms of CBT. PMHC uses variations of a "matched care" approach in which the treatment offered is based on a cooperative decision between client and therapist. In Sandnes, most clients started with a four-session psychoeducational course. This was common in Kristiansand as well, although not as systematically implemented as in Sandnes. Despite growing evidence of guided self-help as an effective treatment form for anxiety and depression [26–29] and the Directorate of Health's requirement to offer low-intensity treatments when indicated, self-help programs were to a little extent readily available during the trial period. Materials available throughout the trial were paper-based programs developed by other PMHC centers. Towards the end of the data collection period, various internet-based programs were increasingly used via a website developed by Norwegian psychologists (www.assistertselvhjelp.no). This website offers specific guided self-help programs for anxiety, depression, stress, and sleep difficulties. No extra resources were added to or amendments conducted of the PMHC service delivery during the trial.

Interventions: TAU. TAU included all ordinary services available to the target population. In the two included municipalities, this usually included follow-up by the GP, or alternatively by private psychologists or occupational health services. After randomization, the TAU group received a response letter in which they were encouraged to contact the GP for further follow-up as well as references to publicly available self-help resources (internet, books).

Fidelity Evaluation. To assess the fidelity of the treatment offered in PMHC, sessions were routinely recorded on audio tape. A random selection of 10 individual treatment sessions and 5 group courses (3 from Kristiansand and 2 from Sandnes) were extracted and rated regarding therapeutic competence and adherence using the Cognitive Therapy Adherence and Competence Scale (CTACS) [30]. The CTACS consists of 25 items measuring adherence (scale ranging from 0 "none" to 6 "thorough") and 25 items measuring competence (scale ranging from 0 "poor" to 6 "excellent"). It was difficult to differentiate between adherence and competence empirically, and therefore a single overall mean fidelity score is reported. Sufficient fidelity was defined as a mean CTACS score >3 [31]. For individual sessions 2 items were considered not applicable in the PMHC context and were therefore excluded, namely item 17 ("Eliciting core beliefs and schemas") and item 20 ("Case conceptualization: Linking past to present"). The group course sessions were given as lectures, and items measuring interaction between therapist and client were therefore considered less relevant, leaving only 5 items to assess: item 3 ("Bridge from previous visit"), item 9 ("Focus/structure"), item 10 ("Socialization to cognitive therapy model, concept or process"), item 24 ("Alternative cognitive and behavioral techniques"), and item 25 ("Overall performance as a cognitive therapist"). One expert rater and a trained psychology student assessed the 10 individual sessions independently. None of the raters were involved in the actual treatment. The intraclass correlation derived from a two-way mixed-effects model (consistency, single rater/measurement) was 0.82, indicating excellent agreement according to Cicchetti's (1994) guidelines [32]. The mean CTACS score was 2.8 (SD = 0.7) for the individual sessions and 3.5 (SD = 0.3) for the group sessions. These results suggest that fidelity to CBT in PMHC was in the sufficient range, but that there is obvious room for improvement. Low mean fidelity scores (<1.5) across individual sessions were observed for the following aspects of CBT: item 1 ("Setting agenda"), item 5 ("Reviewing previous homework"), and item 21 ("Sharing the conceptualization with the patient").

Data Collection during Follow-Up. Clients assigned to the PMHC group were asked to complete questionnaires before each session during the treatment, after treatment, and at 6-month follow-up. Clients assigned to the TAU group were asked to complete questionnaires at 3- and 6-month follow-up. A 3-month follow-up was constructed for the PMHC group to align with the 3-month follow-up of the TAU group. Scores observed under PMHC treatment between 10 and 14 weeks after baseline were used for this purpose (n = 197). If a client reported multiple scores between 10 and 14 weeks, the latest observed score was assigned to the 3-month follow-up measure. For clients who terminated treatment prior to 10 weeks, the posttreatment score was carried forward to 3-month follow-up under the assumption of short-term stability (n = 41). For each PMHC participant, the therapists completed a questionnaire at posttreatment about the therapy process. Electronic questionnaires were used, with a paper version available by client preference (used in exceptional cases). Except for the "under treatment" questionnaires, the participants were invited through standardized e-mails with direct, secure links to the online questionnaires. One e-mail reminder was used throughout the study period for both groups. From the start of the project, one telephone reminder was also used. By requirement from the ethics committee, due to insufficient specification in the project application, the telephone reminder was replaced by a standardized SMS from March 2017. The TAU group received gift cards as compensation for filling in follow-up questionnaires (up to USD 50 for completing all follow-ups).

Primary Outcomes

The primary outcomes were symptoms of depression and anxiety at 6-month follow-up. In line with previous publications [21, 25], this was expressed in terms of (reliable) recovery rates and mean levels of depression and anxiety (see below for a more detailed operationalization).

Symptoms of Depression (PHQ-9). In the PHQ-9, participants were asked how often during the last 2 weeks they had experienced nine common symptoms of depression, such as "little interest or pleasure in doing things" and "feeling down, depressed, or hopeless" [33, 34]. Participants reported the frequency on a scale from "not at all" (0) to "nearly every day" (3). The PHQ-9 has been shown to have good psychometric properties [33], and in our sample Cronbach's α for the instrument was 0.80. A sum score was created, ranging from 0 to 27.

Symptoms of Anxiety (GAD-7). In the GAD-7 participants were asked to rate how often during the last 2 weeks they had experienced seven common symptoms of anxiety, such as "feeling nervous, anxious or on edge" and "not being able to stop or control worrying" [34, 35]. The frequency was reported on the same scale as for PHQ-9, from "not at all" (0) to "nearly every day" (3). GAD-7 has been found to have good reliability and validity for measuring generalized anxiety disorder [35] and to have satisfactory sensitivity and specificity for generalized anxiety as well as other anxiety disorders [8]. In our sample, Cronbach's alpha for the instrument was 0.83. A sum score was created, ranging from 0 to 21. Recovery was defined as scoring above the caseness threshold on the PHQ-9 (≥10) and/or GAD-7 (≥8) measures at the start of treatment and below the caseness threshold on both these measures at follow-up. The reliable recovery rate was calculated in order to account for measurement error, aligning with the procedures employed for the IAPT evaluations [20]. Using the SD of the sample and Cronbach's alpha for PHQ-9 and GAD-7, a change score of ≥6 was derived for PHQ-9 and ≥5 for GAD-7. A client was defined as reliably recovered when scoring below threshold on both measures at follow-up and showing reliable improvement on either PHQ-9 or GAD-7.

Secondary Outcomes

Work Participation. Work participation was assessed by means of two questions, one multiresponse item about current work status and one multiresponse item about sources of income. Based on these two questions, it was determined whether participants were in full- or part-time regular work without receiving benefits or not (coded as a binary variable).

Functional Status. The Work and Social Adjustment Scale (WSAS) [36] was used to measure functional status. The WSAS contains 5 items assessing impairment due to mental health problems during the last month in the domains work/studies, home management, social leisure activities, private leisure activities, and personal relationships. Responses are given on a 9-point scale (0 = not impaired to 8 = severely impaired). A higher sum score (0–40) indicates more impairment. The WSAS has been employed in previous evaluations of PMHC [24] and IAPT [20] and has in this context shown discriminant validity to, and comparable reliability and sensitivity to change as, the PHQ-9 and GAD-7 [37].

Health-Related Quality of Life. The EQ-5D [38] was used to measure health-related quality of life. The paper version was largely completed electronically; a dedicated digital version of the EQ-5D was not used. It is a validated, generic questionnaire that measures health status in terms of five dimensions: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Lower scores indicate higher levels of health-related quality of life. Depression was found to substantially impact on health-related quality of life as measured by the EQ-5D among primary care clients [39].

Mental Well-Being. We employed the Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS) [40]. The scale contains 7 items measured on a scale ranging from 1 (none of the time) to 5 (all the time), such that a high score indicates high levels of positive mental well-being. The psychometric properties of the scale are satisfactory [41, 42], including in the PMHC setting [43].

Serious Adverse Events. Information about serious adverse events was collected by assessing the therapy process forms in the PMHC group, which included open fields for recording reasons for ending treatment and/or referring the client to other services. We defined such events as suicidal behavior or hospitalization that were suspected to be related to the interventions provided.

Statistical Methods

Power and Sample Size. Under the conservative assumption that the recovery rate (PHQ-9 score <10 and GAD-7 score <8) after 6 months is 30% in the control group and 50% in the intervention group, the number of participants required would be 155 in the PMHC group and 67 in the TAU group (with an allocation ratio of 0.3/0.7, an alpha set to 0.05, and a power of 0.80). A 50% recovery rate is equal to the target recovery rate for IAPT, whereas a 30% recovery rate for the control group was based on the assumption that the majority of PMHC clients (70%) will have experienced anxiety or depression for over 6 months before PMHC treatment [21]. As described above, the recovery rates in these clients were found to not exceed 20% with no or minimal intervention [44–46]. For clients with anxiety and depression for <6 months, the natural recovery rate is around 50% [44]. Together this gives an expected recovery rate in the TAU group of around 30% ($0.7 \times 0.2 + 0.3 \times 0.5$). To account for an expected attrition rate of 20% at 6-month follow-up, the required sample size is 277. To increase power for subgroup analyses, we aimed for a sample size of $4 \times 277 = 1{,}108$ [47].

Main Analyses. Baseline data were reported descriptively and across groups without using formal statistical tests. Multiple imputation was used to estimate (reliable) recovery rates at 3- and 6-month follow-up. In the first step, 200 datasets containing eight variables (PHQ-9 at 3 time points, GAD-7 at 3 time points, site, and group) were generated using Bayesian analysis (MCMC algorithm). In the second step, (reliable) recovery was conditioned on site and group using robust maximum likelihood. Model estimates were used to derive (reliable) recovery rates by treatment group. The odds ratio (OR) of the treatment effect was transformed to a d family effect size by applying the formula $d = \ln(\mathrm{OR}) \times \sqrt{3}$ [48]. The numbers needed to treat were also calculated. In line with recommendations from Guidi et al. [49], the percentages of clients by group who reliably deteriorated between baseline and 6-month follow-up were also reported, defined as an increase in PHQ-9 score ≥6 or GAD-7 score ≥5 (see also the definition of the reliable recovery rate). To examine the specific effects of PMHC on depression and anxiety, the continuous outcome scores of PHQ-9 and GAD-7 were modeled by means of piecewise growth models, in which fixed slopes were estimated for the periods baseline to 3 months and 3 months to 6 months. Only clients with clinically significant scores at baseline were included in these models (≥10 for PHQ-9, $n = 616$; ≥8 for GAD-7, $n = 590$). For all models, site (Kristiansand versus Sandnes) and group (PMHC versus TAU) were included as fixed effects. Between-group effect sizes (d) were calculated by dividing the mean difference in estimated change scores from baseline to 6 months by the SD at baseline. Robust

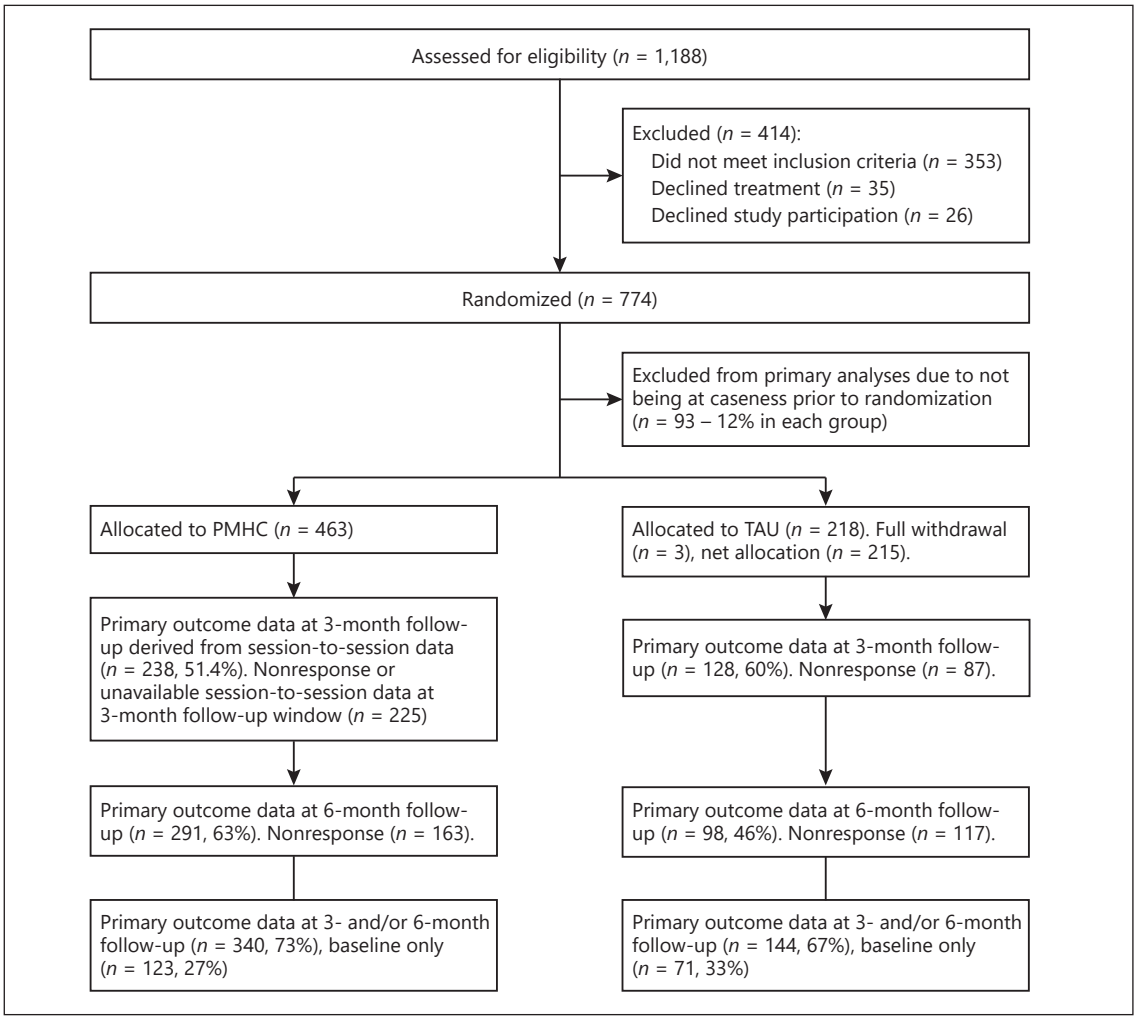

Fig. 1. Flow diagram of PMHC for the period November 9, 2015 to August 31, 2017. PMHC, Prompt Mental Health Care; TAU, treatment as usual.

maximum likelihood was used as estimator, providing unbiased estimates under the assumption of data missing at random [50].

Additional Analyses. Sensitivity analyses were performed to examine the impact of missing data at follow-up under various missing not at random conditions, employing both pattern mixture and selection models [50]. These models rely on fundamentally different assumptions, i.e., pattern mixture models (PMMs) assume that outcome scores are conditional on missingness, whereas selection models assume that missingness is conditional on the observed outcomes scores. A single binary missing data indicator variable was used for all sensitivity analyses and was defined as follows: 0 = complete outcome data on all three measurement occasions (full response group), 1 = incomplete outcome data at 3- and/or 6-month follow-up (incomplete response group). The first PMM (PMM1) was used to generate separate effect estimates for the full and incomplete response group by means of the multiple group and known class options in Mplus. Model constraints were applied to calculate the weighted average of the effect estimates over the two groups. As reasons for nonresponse may differ between the treatment and control groups, a second PMM (PMM2) was developed, extending the previous model by also stratifying by treatment group. That is, change was estimated separately in four different groups (PMHC full response group, PMHC incomplete response group, TAU full response group, TAU incomplete response group), followed by the calculation of a weighted average effect estimate. The final PMM (PMM3) was extended further by using information provided by the therapists after treatment. Therapists provided information on whether the client dropped out from treatment prematurely or not. Moreover, for those who completed treatment, therapists were asked whether or not the therapeutic goal was achieved. The observed data indicated that these three groups (premature dropout, treatment completed but therapeutic goal not achieved, treatment completed and therapeutic goal achieved) developed differently over time. In combination with the binary missing data indicator variable, change was estimated separately in seven groups (PMHC full response group and achieved therapeutic goal, PMHC full response group and did not achieve therapeutic goal, PMHC incomplete response group and

Table 2. Baseline characteristics by treatment group

Characteristics at baseline	PMHC (n = 463)	TAU (n = 215)	Total (n = 678)
Age, years	34.6±11.8	35.3±13.1	34.8±12.2
Women	65.7 (304)	68.4 (147)	66.5 (451)
Higher education	43.9 (280)	36.6 (78)	41.6 (280)
Having a partner	55.1 (254)	58.9 (126)	56.3 (380)
Being in regular work	37.1 (172)	38.1 (82)	37.5 (254)
Immigration background	12.6 (58)	9.3 (20)	11.5 (78)
Depression severity	14.9±4.3	15.0±4.3	14.9±4.4
Depression, PHQ-9 score ≥10	90.1 (417)	92.6 (199)	90.9 (616)
Anxiety severity	12.1±4.2	11.9±4.2	12.0±4.2
Anxiety, GAD-7 score ≥8	87.0 (403)	87.0 (187)	87.0 (590)
Daily use of antidepressants	15.4 (67)	14.7 (30)	15.2 (97)
Weekly use of sleep medication	16.4 (72)	17.4 (36)	16.7 (108)
Weekly use of anxiolytic medication	7.6 (32)	6.0 (12)	7.1 (44)
Having elevated symptoms ≥6 months prior to baseline	86.8 (401)	88.8 (191)	87.3 (592)
Having symptoms at baseline level ≥6 months prior to baseline	66.6 (307)	68.5 (146)	67.2 (453)
Sought help for similar problems during the last 12 months prior to baseline	22.5 (104)	20.5 (44)	21.9 (148)

The descriptive statistics represent percentages (numbers) or means ± standard deviations. GAD-7, Generalized Anxiety Disorder scale; PHQ-9, Patient Health Questionnaire; PMHC, Prompt Mental Health Care; TAU, treatment as usual.

achieved therapeutic goal, PMHC incomplete response group and did not achieve therapeutic goal, PMHC dropouts, TAU full response group, TAU incomplete response group). This was again followed by the calculation of a weighted average effect estimate. Selection model 1 was defined by extending the standard missing at random models by regressing the binary missing data indicator variable on group (PMHC versus TAU) and on the observed outcome scores at baseline, 3-month, and 6-month follow-up. Selection model 2 added interaction effects between group and the observed outcome scores. The interactions were modeled by means of a multiple group model (known class = group [PMHC, TAU]). For the secondary outcomes, piecewise growth models similar to those presented in the main analyses section were applied. The intention-to-treat principle was applied to all outcome analyses. The data were prepared and descriptive analyses performed using SPSS v.24 and Stata v.15. The main analyses were conducted using Mplus v.8.

Results

Recruitment and Participant Flow

The participant flow throughout the trial is visualized in Figure 1. Between November 9, 2015 and August 31, 2017, 1,188 clients were assessed for eligibility. Of these, 774 (92.7% of those eligible) were randomized; 35 declined treatment and 26 declined trial participation. We subsequently excluded 93 clients from the primary analyses as they were not at caseness prior to randomization. Thus, 463 clients (68.0%) were allocated to PMHC and 218 (32.0%) to TAU. From the TAU group 3 requested full withdrawal, yielding a net allocation of 215 clients to TAU.

The recruitment period stopped in August 2017, primarily as the funding of the services from the Norwegian Directorate of Health ended in December 2017, while further local funding remained unclarified. The reason for not fully reaching the sample expected by this time was periods of varying inflow of clients and capacity at both sites due to sick leaves, maternity leave, and turnover. The 6-month follow-up was finalized on March 1, 2018.

Altogether slightly more outcome data were available in the PMHC than the TAU group (data available at 3- and/or 6-month follow-up for 73 vs. 67%, respectively, see Fig. 1). Missing data on PHQ-9 and GAD-7 at 3- and/or 6-month follow-up were associated with the baseline variables sex, age, education, marital status, and reporting relationship problems as cause of symptoms at the $p < 0.05$ level in simple logistic regression analyses. These findings provide some support that the missing data may partly be missing at random. The associations of these variables with the outcome variables were also relatively weak ($r < 0.2$), and including them as auxiliary variables would therefore have had negligible effects. The correlations between observed PHQ-9 and GAD-7 at baseline and 3- and 6-month follow-up were also relatively weak

Table 3. Exposure to treatment between baseline and 6-month follow-up by treatment group

	PMHC		TAU	
	n	%	*n*	%
Of total respondents, number of PMHC treatment sessions				
0 sessions	18	4.1	NA	NA
3 sessions or less	83	18.7	NA	NA
4 sessions or more	339	77.2	NA	NA
Received help for mental health problems beyond PMHC since baseline	60	21.6	54	58.7
Of these, received help for the same or other mental health problems				
Other	8	13.6	3	5.6
Both same and other	16	27.1	7	13.0
Same	35	59.3	44	81.4
Of total respondents, at least one session with				
General practitioner	40	14.9	39	47.0
Psychologist/psychiatrist	23	8.6	32	38.6
Other municipality mental health care service	2	0.8	8	9.6
Other services	14	5.2	6	7.2
Of total respondents, number of sessions beyond PMHC				
0 sessions	218	78.4	38	41.3
3 sessions or less	14	5.0	4	4.4
4 sessions or more	36	13.0	41	44.6
Unknown number	10	3.6	9	9.8

Listwise deletion of missing responses. NA, not applicable; PMHC, Prompt Mental Health Care; TAU, treatment as usual.

($r \sim 0.3$). Even though PHQ-9/GAD-7 at baseline were included in all the models estimating the effect of treatment, the weak correlations with outcome at follow-up reduced the possibility to correct for bias in case of missing not at random data [50]. Sensitivity analyses as reported below may therefore be of even greater importance. It should be noted that among those completing the questionnaires, the missing data rates of individual items were very low at all measurement occasions (<1%).

Baseline Characteristics

As displayed in Table 2, baseline demographic and clinical characteristics were generally similar across the two treatment groups. In total, two-thirds of the participants were women, mean age was 34.8 (SD = 12.2) years, and 11.5% reported to have an immigrant background. Nearly half (41.6%) had higher education and 37.5% reported to be in regular work.

For PHQ-9 and GAD-7 90.9 and 87.0%, respectively, scored above clinical cutoffs, with mean severity scores of PHQ-9 = 14.9 (SD = 4.4) and GAD-7 = 12.0 (SD = 4.2). Only a minority reported use of psychotropic medicine (Table 2). The majority (87.3%) reported having had elevated symptoms at least 6 months prior to baseline, while only 21.9% reported to have sought help for similar problems as presented during the last 12 months. In the PMHC group, the therapists reported 38.3% to have depression, 19.2% to have anxiety, and 42.6% to have mixed anxiety and depression as a provisional diagnosis. Provisional diagnoses were not set in the TAU group, but were, due to the random allocation, considered not to be systematically different from those of the PMHC group.

Exposure to Treatment

PMHC. As reported by the therapist (information available for 95.7% of clients), the PMHC group received a median of 5 (IQR = 4–9) treatment sessions. In total, 95.9% received at least one treatment session (assessment not included), 85.8% received at least two treatment sessions (assessment not included), and 76.9% completed treatment (defined as the therapist reporting that the treatment goal was fulfilled and/or completing at least six sessions). Of the 107 (23.1%) clients dropping out of treatment, the therapists reported that 15.9% were referred to secondary services and

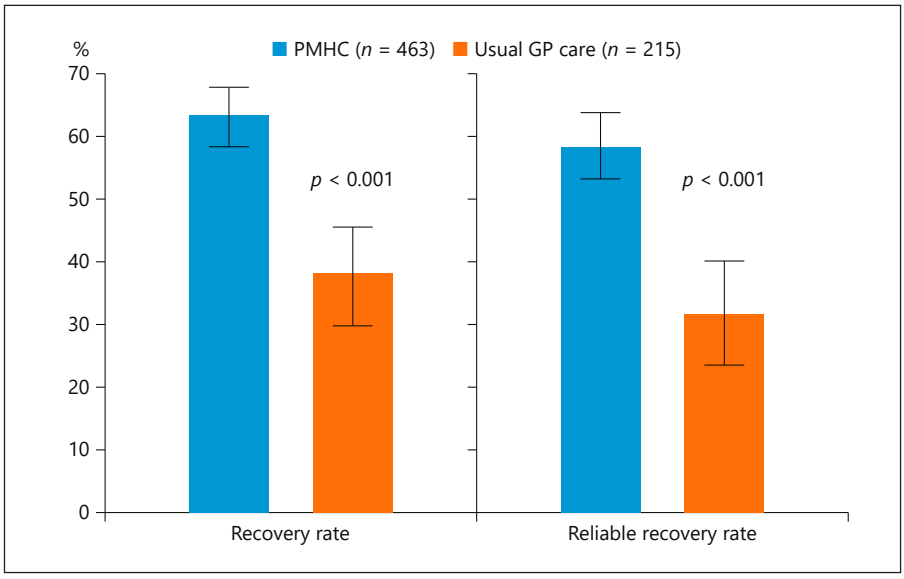

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Fig. 2. Recovery rate by treatment group at 6-month follow-up. GP, general practitioner; PMHC, Prompt Mental Health Care.

24.3% were no longer motivated for treatment. For 40.2% other reasons for dropping out of treatment were reported, while the reason for dropout was unknown for the remaining 19.6%. In total, 35.1% received primarily group-based psychoeducation, 30.0% primarily individual CBT, and 0.9% primarily guided self-help. The remaining 34.0% received a mixture of these treatment forms. The median number of treatment sessions was lowest for guided self-help (1.5, IQR = 1–5), medium for group-based psychoeducation (4, IQR = 3–4), and highest for individual CBT (7, IQR = 4–10) and mixed treatment (9, IQR = 7–12). At 6-month follow-up, 21.6% of participants in the PMHC group reported to have received help for their mental health problems also from others since baseline. The majority of these (86.4%) had received help for the problems reported as the reason for their first contact with PMHC. This additional contact was primarily with the GP (Table 3). In sum, 5.0% reported to have received three sessions or less and 13.0% at least four sessions with other services than PMHC, whereas the number of sessions was unknown for the remaining 3.6%.

TAU. Of the respondents, 58.7% reported having received help for mental health problems from others between baseline and 6-month follow-up, whereof the vast majority were due to the same problems as they contacted PMHC for (94.4%). Most reported follow-up by the GP or a psychologist/psychiatrist (Table 3). In sum, 41.3% of TAU respondents had received no help, 4.4% three sessions or less, and 44.6% at least four sessions with alternative services since first contact with PMHC, whereas the number of sessions was unknown for the remaining 9.8%. Overall, these numbers suggest that the vast majority of participants in the PMHC were exposed to treatment between baseline and 6-month follow-up, which was primarily delivered by PMHC therapists. In contrast, only a bit more than half of the participants in the TAU group received some form of treatment between baseline and 6-month follow-up, and about half of the sessions in the TAU group consisted of GP contacts. Although treatment in the TAU group did not equal "no treatment," exposure to comparable forms of evidence-based psychotherapy was limited.

Primary Outcomes

Recovery Rates and Reliable Recovery Rates at 6-Month Follow-Up. The recovery rate and reliable recovery rate by treatment group at 6-month follow-up is visualized in Figure 2. The recovery rate was 63.5% (95% CI 58.4 to 68.6%) in the PMHC group and 38.3% (95% CI 29.7 to 46.9%) in the TAU group. This gave a between-group effect size in favor of the PMHC group of 0.57 (95% CI 0.33 to 0.81), $p < 0.001$. The corresponding reliable recovery rate was 58.5% (95% CI 53.2 to 63.7) in the PMHC group and 31.9 (95% CI 23.6 to 40.1) in the TAU group, yielding a between-group effect size of 0.61 (95% CI 0.37 to 0.85), $p < 0.001$. The numbers needed to treat were 4.03 (95% CI 2.28 to 5.78) based on the recovery rate estimates and 3.81 (95% CI 2.30 to 5.32) based on the *reliable* recovery rates estimates. The estimated proportion of clients who

Table 4. Continuous outcome estimates at baseline, 3-month, and 6-month follow-up

	Group	Baseline	3 months	6 months	Effect size[1]
Primary outcomes					
Depressive symptoms	PMHC (n = 417)	15.72 (15.34, 16.09)	8.26 (7.44, 9.08)	7.45 (6.62, 8.30)	–0.88** (–1.23, –0.43)
	TAU (n = 199)	15.57 (15.03, 16.12)	10.78 (9.82, 11.75)	11.15 (9.90, 12.40)	
Anxiety symptoms	PMHC (n = 403)	13.13 (12.80, 13.45)	6.80 (6.02, 7.57)	5.88 (5.16, 6.59)	–0.60** (–0.90, –0.30)
	TAU (n = 187)	12.85 (12.33, 13.37)	8.78 (7.95, 9.61)	8.27 (7.31, 9.23)	
Secondary outcomes					
Functional status	PMHC (n = 463)	21.77 (21.07, 22.47)	–	12.58 (10.98, 14.13)	–0.39* (–0.68, –0.10)
	TAU (n = 215)	21.40 (20.32, 22.48)	–	15.96 (13.96, 17.97)	
Health-related quality of life	PMHC (n = 463)	10.93 (10.68, 11.19)	8.48 (8.02, 8.95)	8.20 (7.73, 8.67)	–0.46** (–0.69, –0.23)
	TAU (n = 215)	10.86 (10.51, 11.21)	9.38 (8.91, 9.85)	9.59 (8.99, 10.19)	
Positive mental well-being	PMHC (n = 463)	18.27 (17.93, 18.60)	22.92 (22.13, 23.71)	23.94 (23.19, 24.70)	0.65** (0.35, 0.95)
	TAU (n = 215)	18.41 (17.91, 18.91)	20.84 (20.02, 21.65)	21.29 (20.27, 22.31)	

The values represent means (95% CIs). For depressive symptoms, clients with a PHQ-9 score <10 at baseline were excluded. For anxiety symptoms, clients with a GAD-7 score <8 at baseline were excluded. GAD-7, Generalized Anxiety Disorder scale; PHQ-9, Patient Health Questionnaire; PMHC, Prompt Mental Health Care; TAU, treatment as usual. [1] Between-group effect size at 6-month follow-up. * $p < 0.01$, ** $p < 0.001$.

reliably deteriorated was 1.3% (95% CI 0.1 to 2.5%) in the PMHC group and 4.2% (95% CI 0.9 to 7.6%) in the TAU group, which equaled a between-group effect size of –0.65 (95% CI –1.36 to –0.06, p = 0.07). No serious adverse events were reported.

Change in Depressive and Anxiety Symptoms from Baseline to 3- and 6-Month Follow-Up. As detailed in Table 4, a clear symptom reduction was observed for both groups in both depression and anxiety between baseline and follow-up. More specifically, the estimated mean PHQ-9 score changed from 15.72 at baseline to 7.45 at 6-month follow-up in the PMHC group and from 15.57 to 11.15 in the TAU group. This gave a between-group effect size at 6-month follow-up of –0.88 (95% CI –1.23 to –0.43) in favor of the PMHC group. This effect size represents the effect of PMHC as compared to TAU on depressive symptoms for those participants with clinically relevant symptom levels of depression at baseline (PHQ-9 score ≥10). For GAD-7 the mean score changed from 13.13 to 5.88 in the PMHC group and from 12.85 to 8.27 in the TAU group during the same period, yielding a between-group effect size of –0.60 (95% CI –0.90 to –0.30). This effect size represents the effect of PMHC as compared to TAU on symptoms of anxiety for those participants with clinically relevant symptom levels of anxiety at baseline (GAD-7 score ≥8).

Sensitivity Analyses. Figure 3 depicts between-group effect sizes at 6-month follow-up across sensitivity analyses performed. Overall, all analyses pointed in the same direction, in favor of PMHC, and there were relatively small variations in point estimates. The results were ro-

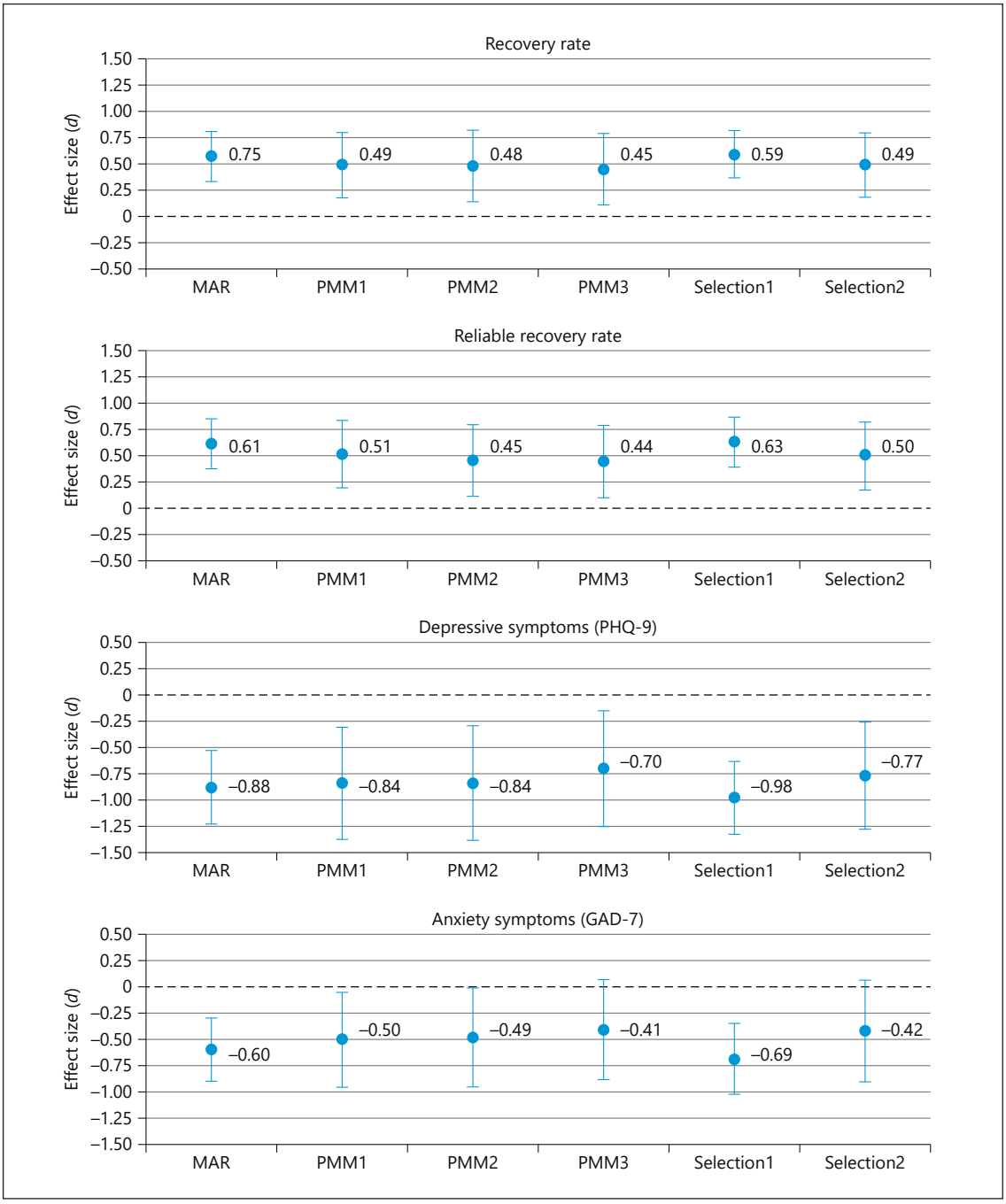

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Fig. 3. Between-group effect sizes across sensitivity analyses and outcome variables at 6-month follow-up. Error bars represent 95% CIs. GAD-7, Generalized Anxiety Disorder scale; MAR, missing at random; PHQ-9, Patient Health Questionnaire; PMM, pattern mixture model (see Statistical Methods for a more detailed description); Selection, selection model.

bust across analyses for recovery rate, reliable recovery rate, and depressive symptoms (PHQ-9), as indicated by no CIs crossing nonsignificance. For anxiety symptoms (GAD-7), however, the CIs crossed zero for the two most conservative models (PMM3 and selection model 2). Thus, the effect of PMHC as compared to TAU on symptoms of anxiety was somewhat more uncertain given the data from the present study.

Secondary Outcomes

Based on the current data, there was no evidence for an effect of PMHC on job participation. At 6-month follow-up, the estimated proportion of participants in full- or part-time regular work was 54.5% (95% CI 41.2 to 67.9%) in the PMHC group and 51.8% (95% CI 30.6 to 73.0%) in the TAU group ($z = 0.415$, $p = 0.69$). For the other secondary outcomes, we found between-group differences in favor of the PMHC group (Table 4). At 6-month follow-up, the between-group effect sizes for respectively functional status (WSAS), health-related quality of life (EQ-5D), and positive mental well-being (SWEMWBS) were –0.39 (95% CI –0.68 to –0.10), –0.46 (95% CI –0.69 to –0.23), and 0.65 (95% CI 0.35 to 0.95).

Full Sample Analyses with Inclusion of Participants Not at Caseness at Baseline

One formal inclusion criterion for participation in the study was a PHQ-9 score ≥10 and/or a GAD-7 score ≥8. However, due to the pragmatic nature of the trial, therapists worked according to common practice routines as much as possible. The decision to include or exclude a client from participation/access to the service was therefore not merely based on scoring above a cutoff value, but also on clinical judgement. As a result, 93 clients who were not at caseness at baseline were included in the study and subsequently randomized to PMHC or TAU. Including participants scoring below the cutoffs of PHQ-9 and/or GAD-7 at baseline did not substantially alter the main findings presented above, but naturally resulted in somewhat lower between-group effect size estimates for the continuous outcome measures, $n = 770$ for all analyses (PHQ-9: ES = –0.63, 95% CI –0.85 to –0.41, $p < 0.001$; GAD-7: ES = –0.43, 95% CI –0.61 to –0.25, $p < 0.001$; WSAS: ES = –0.42, 95% CI –0.75 to –0.18, $p = 0.001$; EQ-5D: ES = –0.46, 95% CI –0.66 to –0.26, $p < 0.001$; SWEMWBS: ES = 0.65, 95% CI 0.40 to 0.90, $p < 0.001$). By definition, the results for the recovery rates were unchanged, and the effect on work participation remained statistically nonsignificant ($z = 0.19$, $p = 0.69$).

Discussion and Conclusion

Principal Findings

This study is the first to evaluate the effectiveness of an IAPT-like treatment model in terms of a randomized controlled trial. The Norwegian adaption, PMHC, was substantially more effective than TAU in alleviating symptoms of depression and anxiety at 6-month follow-up among adults with symptoms of anxiety and/or mild to moderate depression. More specifically, the 6-month reliable recovery rate was 58.5% in the PMHC group and 31.9% in the TAU group, yielding a between-group effect size of 0.61. The differences in degree of symptom improvement equaled a between-group effect size of 0.88 for depression and of 0.60 for anxiety. Sensitivity analyses showed that the results were robust across test performed, though slightly more robust for depression than anxiety. PMHC was also more effective than TAU in improving functional status, health-related quality of life, and mental well-being, indicated by medium between-group effect sizes. Based on the self-report data available, improvement in work participation did not differ between PMHC and TAU.

Interpretation

A newly published meta-analysis of the effectiveness of psychotherapies for primary depression and anxiety care found an overall moderate treatment effect of CBT at posttreatment ($d = 0.47$) in most studies compared to TAU [51]. Similar effect sizes were found in a meta-analysis examining the effectiveness of multimodal CBT (i.e., like provided in PMHC) in primary care [52]. Both meta-analyses, and in particular the latter, were mostly based on small sample sizes and high-quality, well-powered studies were called for. The current results thus align well with and extend existing knowledge about the effectiveness of CBT treatment in primary health care contexts.

Our findings should be considered robust for at least three reasons. Firstly, they are based on 6-month follow-up while the mentioned meta-analyses were based on posttreatment results. A 2013 meta-analysis found lower effects at 6-month follow-up ($d = 0.29$) than at posttreatment ($d = 0.57$) [53]. However, few such follow-up studies have been conducted, further underscoring the importance of the current study. Secondly, PMHC was compared to TAU, whereof about half of the respondents reported to have received at least four sessions at alternative services for their mental health problem. Most of this follow-up was by a GP or psychologist/psychiatrist. Previous studies have found considerably lower effect sizes for TAU than other controls implying less follow-up, such as waiting lists or placebo [53]. Finally, the achievement of the PMHC sites is impressive seen against the obstacles met during the project phase. These included uncertainty regarding long-term funding of both services and several changes in project management at one of the sites. Also, few self-help and group treatment programs were readily available, and substantial time was devoted

especially during start-up to establish the content for these treatment types.

The external validity and applicability of the results are considered high due to the pragmatic nature of the trial and the fact that almost all eligible clients were included (92.7%), with a negligible number of full withdrawals ($n = 3$). These aspects furthermore provide positive indications for the acceptability of the intervention. The findings therefore complement and perhaps also validate the findings from the evaluation of the first 12 PMHC pilot sites where participation rates were lower (on average 61%) [21, 25]. The appropriateness of such a generalization is strengthened by the fact that only modest variations in degree of symptom improvement were observed across the sites, despite for instance including both rural and urban areas and variations in demographic compositions [24]. The findings may not hold for sites with a high proportion of immigrants, though. This group was underrepresented in the initial PMHC evaluation and showed somewhat lower symptom reduction during the PMHC treatment than ethnic Norwegians [21].

The results from the present study also seem highly relevant for other countries offering IAPT-like treatments, as many of the features of the treatment model and the operationalization of primary outcomes are common. As previously discussed [21], cross-country comparisons should nonetheless be done with caution, mainly due to differences in health care systems, partly different client populations, and variation in treatment models provided (e.g., variations of stepped and matched care approaches). It would therefore be of tremendous value to test whether the current results can be replicated in other countries.

The sensitivity analyses indicated slightly more robust findings for depressive than anxiety symptoms, and effect sizes were overall higher for depression than anxiety. This seemingly contrasts with the results in Zhang et al.'s meta-analysis [51] where symptom type (anxiety versus depression) did not moderate effect sizes. Notably, when examining standardized change scores by provisional diagnosis, the changes for GAD-7 among those with anxiety as a provisional diagnosis were of similar size as for PHQ-9 among those with depression as a provisional diagnosis (results not shown). As the overall change scores across diagnostic groups were reported in this study and far fewer had anxiety than depression as a provisional diagnosis, this may thus have underestimated the effect of PMHC on symptoms of anxiety, i.e., clients with depression as a provisional diagnosis were characterized by relatively high baseline scores on PHQ-9 and relatively low baseline scores on GAD-7. The changes in GAD-7 scores from baseline to 6-month follow-up were therefore naturally lower in this subgroup, which in turn resulted in a lower average change score for GAD-7 across the PMHC group as a whole. A similar line of reasoning could be applied to the overall effect on PHQ-9, but given the relatively low prevalence of anxiety as a provisional diagnosis, this impact is likely smaller. As data on provisional diagnosis were not available for the control group, effectiveness could not be tested within each subgroup, and the argument put forward in this paragraph should therefore be considered as hypothesis generating.

Symptom reduction constitutes one of several aspects of recovery [54]. Effects on functional outcomes may be considered particularly informative in addition to symptomatology when evaluating low-threshold interventions where no formal diagnosis is set, such as in PMHC. From both a personal and a societal, health economic view it is therefore reassuring that medium-sized effects of PMHC were also found for the secondary outcomes social and work-related function, mental well-being, and health-related quality of life. The effect sizes are in the upper range of what is found in meta-analyses on the effects of psychotherapy for depression on social functioning [55] and quality of life [56].

The result regarding work status is regarded as inconclusive. If a true effect exists, it is likely to be smaller than the effects on anxiety and depression, as the causes for not being in regular work are multiple and common mental health problems are only one factor in this equation. Methodological issues concerning missing data and self-reported work status had as such a negative impact on statistical power. It is in this respect important to highlight that even a small effect on work participation may have a large societal, health economic impact [57]. Additionally, as changes in function often lag symptom changes [54, 58], the 6-month follow-up might have been too short to show a meaningful effect. The planned registry data linkage will yield more precise and complete data over time and enable us to investigate the impact on work participation in more detail and with greater statistical power.

Strengths and Limitations

First and foremost, an important strength of the study is its use of a randomized controlled study design, decreasing the risk of selection bias. The trial followed a strict protocol, including important features such a computerized random number generator for randomization, well-powered sample, and fidelity assessment of the

PMHC treatment, all contributing to the internal validity of the results. The procedures were developed in close collaboration with the involved PMHC centers and procedures approximated routine care as far as possible. This may have increased the external validity and thus also the applicability of the results. Moreover, we used validated instruments with high Cronbach's alphas, the same as employed within IAPT, facilitating cross-county comparisons of the effectiveness of the services.

The most important source of potential bias were missing outcome data. Therefore, we aimed at carefully considering sources and patterns of missingness and performed several sensitivity analyses. Best practice approaches were employed to test the robustness of the results. Reassuringly, all sensitivity analyses pointed in the same direction and had effect sizes of similar magnitude. Thus, the estimated effects of PMHC are not likely explained by selection bias. Nonetheless, as the findings were slightly more robust for depression than anxiety, future studies should investigate the impact of PMHC on anxiety more thoroughly.

Due to the nature of the treatment, blinding was not possible. To lower the risk of bias due to knowledge about assignment, the intake assessors were trained according to a strict protocol to provide a balanced presentation of the treatment alternatives, and GPs were thoroughly informed about the rationale of the study and the randomization process. It can, however, not be precluded that lack of blinding may have affected the treatment provided to the TAU group. For instance, some GPs might have offered more help than usual care, though their tight time schedule indicated that such co-intervention is not likely to have had a substantial impact. Response bias, with the control group reporting too severe symptoms and the PMHC group too light symptoms, is also possible. Given the magnitude of the between-group effect sizes in the present study, it seems unlikely that bias due to nonblinding fully explains the observed effects [59].

TAU included all treatment alternatives available for the target group. While we acknowledge the complexity and variation in content of the TAU condition that follows this pragmatic approach, the choice was deliberate to enable good reflection of ordinary care and to increase external validity. More unsettling is the high level of missing (57%) in the TAU group regarding self-reported treatment provided at 6-month follow-up. Nonparticipation bias as well as recall or information bias may have hampered the precision of this measure. Thus, it is difficult to fully evaluate which providers of health care were consulted, what type of treatment was received, and to what extent this in fact reflects routine care. Subsequent linkage to the health care utilization registry (KUHR) and the Norwegian prescription database will yield objective information about the content of TAU with no loss to follow-up. Based on these registry linkages, we will also conduct health economic analyses where the ratio between value and cost will be assessed from both a personal (through gains in quality-adjusted life years) and societal perspective (through a cost-value analysis).

The trial focused on symptomatology, following routine care where usually no formal diagnoses are set. It should be noted that effects on symptom level do not necessarily translate into effects on a diagnostic level. The reported secondary outcomes nonetheless gave indications of effect on function, which is another key aspect in assessing mental disorders. The design included indirect collection of information on serious adverse events only. Due to the established contact with the caregivers in the trial, we consider it, however, reasonable to assume that in most cases serious adverse events would have been reported to us.

Conclusion

Previous studies have reported promising findings of clinical outcomes from PMHC, IAPT, and other IAPT-based services. As all previous evaluations have employed benchmark comparisons, the true effect of PMHC in relation to natural recovery and TAU remains unsettled. The current randomized controlled trial provides more solid evidence in favor of an effect of PMHC on recovery and alleviation of symptoms and improvement in function and quality of life at 6-month follow-up. This adaptation of IAPT is thus considered a viable supplement to the existing health services and can indeed serve to increase access of effective treatment for adults who suffer from anxiety and mild to moderate depression. The effects on work participation and cost-value of the PMHC service need further examination.

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Statement of Ethics

The trial protocol was approved by the Regional ethics committee for Western Norway (REK-vest No. 2015/885) and the trial is registered at ClinicalTrials.gov (NCT03238872). No changes were made to the primary or secondary outcomes after trial approval. All participants gave their written informed consent.

Disclosure Statement

The authors have no conflicts of interest to declare.

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Author Contributions

O.R.F. Smith and M. Knapstad contributed to the design of the study. O.R.F. Smith and M. Knapstad performed the statistical analyses and L.V. Lervik the fidelity evaluation. M. Knapstad and O.R.F. Smith drafted the manuscript. All authors contributed to the interpretation of the data and offered critical revisions of the draft. All authors read and approved the final manuscript.

References

1 Baxter AJ, Scott KM, Vos T, Whiteford HA. Global prevalence of anxiety disorders: a systematic review and meta-regression. Psychol Med. 2013 May;43(5):897–910.
2 Ferrari AJ, Somerville AJ, Baxter AJ, Norman R, Patten SB, Vos T, et al. Global variation in the prevalence and incidence of major depressive disorder: a systematic review of the epidemiological literature. Psychol Med. 2013 Mar;43(3):471–81.
3 Knudsen AK, Tollånes M, Haaland Ø, Kinge JM, Skirbekk V, Vollset SE. Disease Burden in Norway 2015. Results from the Global Burden of Diseases, Injuries, and Risk Factors Study 2015 (GBD 2015). Oslo: Public Health Institute Norway; 2017.
4 Kessler RC, Amminger GP, Aguilar-Gaxiola S, Alonso J, Lee S, Ustün TB. Age of onset of mental disorders: a review of recent literature. Curr Opin Psychiatry. 2007 Jul;20(4):359–64.
5 Knudsen AK, Øverland S, Hotopf M, Mykletun A. Lost working years due to mental disorders: an analysis of the Norwegian disability pension registry. PLoS One. 2012;7(8):e42567.
6 Knudsen AK, Harvey SB, Mykletun A, Øverland S. Common mental disorders and long-term sickness absence in a general working population. The Hordaland Health Study. Acta Psychiatr Scand. 2013 Apr;127(4):287–97.
7 Lerner D, Henke RM. What does research tell us about depression, job performance, and work productivity? J Occup Environ Med. 2008 Apr;50(4):401–10.
8 Kroenke K, Spitzer RL, Williams JB, Monahan PO, Löwe B. Anxiety disorders in primary care: prevalence, impairment, comorbidity, and detection. Ann Intern Med. 2007 Mar;146(5):317–25.
9 Alonso J, Liu Z, Evans-Lacko S, Sadikova E, Sampson N, Chatterji S, et al.; WHO World Mental Health Survey Collaborators. Treatment gap for anxiety disorders is global: Results of the World Mental Health Surveys in 21 countries. Depress Anxiety. 2018 Mar;35(3):195–208.
10 Thornicroft G, Chatterji S, Evans-Lacko S, Gruber M, Sampson N, Aguilar-Gaxiola S, et al. Undertreatment of people with major depressive disorder in 21 countries. Br J Psychiatry. 2017 Feb;210(2):119–24.
11 World Health Organization. The world health report 2001: Mental health: new understanding, new hope. Geneva: World Health Organization; 2001.
12 Community and Mental Health team. Psychological Therapies. Annual report on the use of IAPT services, England 2017–18. London: NHS Digital; 2018.
13 Torvik FA, Ystrom E, Gustavson K, Rosenström TH, Bramness JG, Gillespie N, et al. Diagnostic and genetic overlap of three common mental disorders in structured interviews and health registries. Acta Psychiatr Scand. 2018 Jan;137(1):54–64.
14 OECD. OECD Reviews of Health Care Quality: Norway 2014: Raising standards. Paris: OECD Publishing; 2014.
15 Ose SO, Kaspersen S. Kommunalt psykisk helse- og rusarbeid 2015: Årsverk, kompetanse og innhold i tjenestene. SINTEF-rapport A27362 [Municipality mental health and substance abuse services 2015: FTEs, competence and content for services]. Trondheim: SINTEF; 2015.
16 Helsedirektoratet (Norwegian Directorate of Health): Rask Psykisk Helsehjelp – 12 Pilotkommuner. Veiledende materiell. Oslo, Helsedirektoratet, 2013.
17 Chisholm D, Sweeny K, Sheehan P, Rasmussen B, Smit F, Cuijpers P, et al. Scaling-up treatment of depression and anxiety: a global return on investment analysis. Lancet Psychiatry. 2016 May;3(5):415–24.
18 Jorm AF, Patten SB, Brugha TS, Mojtabai R. Has increased provision of treatment reduced the prevalence of common mental disorders? Review of the evidence from four countries. World Psychiatry. 2017 Feb;16(1):90–9.
19 Parry G, Barkham M, Brazier J, Dent-Brown K, Hardy G, Kendrick T, et al. An evaluation of a new service model: improving access to psychological therapies demonstration sites 2006–2009. NIHR Service Delivery and Organisation Programme, 2011.
20 Clark DM, Layard R, Smithies R, Richards DA, Suckling R, Wright B. Improving access to psychological therapy: initial evaluation of two UK demonstration sites. Behav Res Ther. 2009 Nov;47(11):910–20.
21 Knapstad M, Nordgreen T, Smith OR. Prompt mental health care, the Norwegian version of IAPT: clinical outcomes and predictors of change in a multicenter cohort study. BMC Psychiatry. 2018 Aug;18(1):260.
22 Ellenberg JH. Selection bias in observational and experimental studies. Stat Med. 1994 Mar;13(5–7):557–67.
23 Statistics Norway. Population by region, statistics variable and year, 2019.
24 Smith OR, Alves DE, Knapstad M. Rask Psykisk Helsehjelp: Evaluering av de første 12 pilotene i Norge [Prompt Mental Health Care: Evaluation of the first 12 pilot sites in Norway]. Oslo: Norwegian Institute of Public Health; 2016.
25 Smith OR, Knapstad M, Alves DE, Aarø LE. Initial Results of Prompt Mental Health Care, the Norwegian Version of Improving Access to Psychological Therapies. Psychother Psychosom. 2017;86(6):382–4.
26 Klein JP, Berger T, Schröder J, Späth C, Meyer B, Caspar F, et al. Effects of a Psychological Internet Intervention in the Treatment of Mild to Moderate Depressive Symptoms: Results of the EVIDENT Study, a Randomized Controlled Trial. Psychother Psychosom. 2016;85(4):218–28.

27 Josephine K, Josefine L, Philipp D, David E, Harald B. Internet- and mobile-based depression interventions for people with diagnosed depression: A systematic review and meta-analysis. J Affect Disord. 2017 Dec;223:28–40.
28 Olthuis JV, Watt MC, Bailey K, Hayden JA, Stewart SH. Therapist-supported Internet cognitive behavioural therapy for anxiety disorders in adults. Cochrane Database Syst Rev. 2015 Mar;(3):CD011565.
29 Cuijpers P, Donker T, van Straten A, Li J, Andersson G. Is guided self-help as effective as face-to-face psychotherapy for depression and anxiety disorders? A systematic review and meta-analysis of comparative outcome studies. Psychol Med. 2010 Dec;40(12):1943–57.
30 Barber JP, Liese BS, Abrams MJ. Development of the Cognitive Therapy Adherence and Competence Scale. Psychother Res. 2003; 13(2):205–21.
31 Nordgreen T, Haug T, Öst LG, Andersson G, Carlbring P, Kvale G, et al. Stepped Care Versus Direct Face-to-Face Cognitive Behavior Therapy for Social Anxiety Disorder and Panic Disorder: A Randomized Effectiveness Trial. Behav Ther. 2016 Mar;47(2):166–83.
32 Cicchetti DV. Guidelines, criteria, and rules of thumb for evaluating normed and standardized assessment instruments in psychology. Psychol Assess. 1994;6(4):284–90.
33 Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001 Sep;16(9): 606–13.
34 Kroenke K, Spitzer RL, Williams JB, Löwe B. The Patient Health Questionnaire somatic, anxiety, and depressive symptom scales: a systematic review. Gen Hosp Psychiatry. 2010 Jul–Aug;32(4):345–59.
35 Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006 May;166(10):1092–7.
36 Mundt JC, Marks IM, Shear MK, Greist JH. The Work and Social Adjustment Scale: a simple measure of impairment in functioning. Br J Psychiatry. 2002 May;180(5):461–4.
37 Zahra D, Qureshi A, Henley W, Taylor R, Quinn C, Pooler J, et al. The Work and Social Adjustment Scale: reliability, sensitivity and value. Int J Psychiatry Clin Pract. 2014 Jun; 18(2):131–8.
38 Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. Ann Med. 2001 Jul;33(5):337–43.
39 Sobocki P, Ekman M, Ågren H, Krakau I, Runeson B, Mårtensson B, et al. Health-related quality of life measured with EQ-5D in patients treated for depression in primary care. Value Health. 2007 Mar–Apr;10(2):153–60.
40 Tennant R, Hiller L, Fishwick R, Platt S, Joseph S, Weich S, et al. The Warwick-Edinburgh Mental Well-Being Scale (WEMWBS): development and UK validation. Health Qual Life Outcomes. 2007 Nov;5(1):63.
41 Bartram DJ, Sinclair JM, Baldwin DS. Further validation of the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) in the UK veterinary profession: Rasch analysis. Qual Life Res. 2013 Mar;22(2):379–91.
42 Stewart-Brown SL, Platt S, Tennant A, Maheswaran H, Parkinson J, Weich S, et al. The Warwick-Edinburgh Mental Well-Being Scale (WEMWBS): a valid and reliable tool for measuring mental well-being in diverse populations and projects. J Epidemiol Community Health. 2011;65 Suppl 2:A38–9.
43 Smith OR, Alves DE, Knapstad M, Haug E, Aarø LE. Measuring mental well-being in Norway: validation of the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS). BMC Psychiatry. 2017 May;17(1):182.
44 Posternak MA, Miller I. Untreated short-term course of major depression: a meta-analysis of outcomes from studies using wait-list control groups. J Affect Disord. 2001 Oct; 66(2–3):139–46.
45 Clark DM, Salkovskis PM, Hackmann A, Middleton H, Anastasiades P, Gelder M. A comparison of cognitive therapy, applied relaxation and imipramine in the treatment of panic disorder. Br J Psychiatry. 1994 Jun; 164(6):759–69.
46 Clark DM, Ehlers A, Hackmann A, McManus F, Fennell M, Grey N, et al. Cognitive therapy versus exposure and applied relaxation in social phobia: A randomized controlled trial. J Consult Clin Psychol. 2006 Jun;74(3):568–78.
47 Brookes ST, Whitely E, Egger M, Smith GD, Mulheran PA, Peters TJ. Subgroup analyses in randomized trials: risks of subgroup-specific analyses; power and sample size for the interaction test. J Clin Epidemiol. 2004 Mar;57(3): 229–36.
48 Polanin J, Snilstveit B. Campbell Methods Policy Note on Converting Between Effect Sizes: (Version 11, updated December 2016). Oslo, Norway: The Campbell Collaboration; 2016.
49 Guidi J, Brakemeier EL, Bockting CL, Cosci F, Cuijpers P, Jarrett RB, et al. Methodological recommendations for trials of psychological interventions. Psychother Psychosom. 2018; 87(5):276–84.
50 Enders CK. Applied Missing Data Analysis. New York: The Guilford Press; 2010.
51 Zhang A, Franklin C, Jing S, Bornheimer LA, Hai AH, Himle JA, et al. The effectiveness of four empirically supported psychotherapies for primary care depression and anxiety: a systematic review and meta-analysis. J Affect Disord. 2019 Feb;245:1168–86.
52 Twomey C, O'Reilly G, Byrne M. Effectiveness of cognitive behavioural therapy for anxiety and depression in primary care: a meta-analysis. Fam Pract. 2015 Feb;32(1):3–15.
53 Seekles W, Cuijpers P, Kok R, Beekman A, van Marwijk H, van Straten A. Psychological treatment of anxiety in primary care: a meta-analysis. Psychol Med. 2013 Feb;43(2):351–61.
54 McKnight PE, Kashdan TB. The importance of functional impairment to mental health outcomes: a case for reassessing our goals in depression treatment research. Clin Psychol Rev. 2009 Apr;29(3):243–59.
55 Renner F, Cuijpers P, Huibers MJ. The effect of psychotherapy for depression on improvements in social functioning: a meta-analysis. Psychol Med. 2014 Oct;44(14):2913–26.
56 Kolovos S, Kleiboer A, Cuijpers P. Effect of psychotherapy for depression on quality of life: meta-analysis. Br J Psychiatry. 2016 Dec; 209(6):460–8.
57 Chisholm D, Flisher AJ, Lund C, Patel V, Saxena S, Thornicroft G, et al.; Lancet Global Mental Health Group. Scale up services for mental disorders: a call for action. Lancet. 2007 Oct;370(9594):1241–52.
58 Kennedy N, Foy K, Sherazi R, McDonough M, McKeon P. Long-term social functioning after depression treated by psychiatrists: a review. Bipolar Disord. 2007 Feb–Mar;9(1–2): 25–37.
59 Wood L, Egger M, Gluud LL, Schulz KF, Jüni P, Altman DG, et al. Empirical evidence of bias in treatment effect estimates in controlled trials with different interventions and outcomes: meta-epidemiological study. BMJ. 2008 Mar;336(7644):601–5.