



Long-term outcomes of Prompt Mental Health Care: A randomized controlled trial

Solbjørg Makalani Myrtveit Sæther^a, Marit Knapstad^{a,b,*}, Nick Grey^{c,d}, Marit Aase Rognerud^e, Otto R.F. Smith^a

^a Department of Health Promotion, Norwegian Institute of Public Health, Zander Kaaes Gate 7, 5015, Bergen, Norway

^b Department of Clinical Psychology, University of Bergen, Bergen, Norway

^c Sussex Partnership NHS Foundation Trust, United Kingdom

^d School of Psychology, University of Sussex, United Kingdom

^e Health Section, Oslo Municipality, Oslo, Norway

ARTICLE INFO

Keywords:

Anxiety
Depression
Cognitive behavioral therapy
Randomized controlled trial
Follow-up studies

ABSTRACT

Prompt Mental Health Care (PMHC, Norwegian adaptation of Improving Access to Psychological Therapies) is found successful in alleviating symptoms of anxiety and depression. Here, we investigate whether improvement is maintained over time. A randomized controlled trial was conducted in two PMHC sites from November 2015 to August 2017, randomly assigning 681 adults with anxiety and/or mild to moderate depression (70:30 ratio: PMHC $n = 463$, TAU $n = 218$). Main outcomes were recovery rates and changes in symptoms of depression and anxiety from baseline to 12 months. Secondary outcomes were functional status, health-related quality of life, mental wellbeing and work participation. At 12 months after baseline the reliable recovery rate was 59.4% in PMHC and 36.6% in TAU, giving a between-group effect size of 0.51 (95%CI: 0.26, 0.77, $p < 0.001$). Differences in symptom change gave between-group effect sizes of -0.67 (95%CI: $-0.99, -0.36$, $p < 0.001$) for depression and -0.58 (95%CI: $-0.91, -0.26$, $p < 0.001$) for anxiety. PMHC was also at 12 months found more effective in improving functional status, health-related quality of life and mental wellbeing, but not work participation. In sum, substantial treatment effects of PMHC remain at 12 months follow-up, although results should be interpreted with caution due to risk of attrition bias.

1. Introduction

Anxiety and depression are among the most common mental disorders globally, affecting 1 in 14 (Baxter, Scott, Vos, & Whiteford, 2013) and 1 in 20 (Ferrari et al., 2013), respectively. Also in Norway, anxiety and depression are common in the adult population (Folkhelseinstituttet, 2018), and are estimated to be the 4th and 3rd most important causes of non-fatal health loss (Knudsen et al., 2017), largely due to their high prevalence and early adulthood onset (Kessler et al., 2007). Anxiety and depression are also important causes of functional impairment, including reduced work functioning, sickness absence and

disability pension (Gjesdal, Ringdal, Haug, & Maeland, 2008; Knudsen, Harvey, Mykletun, & Overland, 2013; Knudsen et al., 2010; Knudsen, Overland, Hotopf, & Mykletun, 2012; Kroenke, Spitzer, Williams, Monahan, & Löwe, 2007; Lerner & Henke, 2008).

A large proportion of individuals experiencing anxiety and depression are not receiving adequate care (Alonso et al., 2018; Craske et al., 2017; Kohn, Saxena, Levav, & Saraceno, 2004; Kroenke, Spitzer, Williams, Monahan, & Löwe, 2007; Thornicroft et al., 2017). In order to reduce this treatment gap, the World Health Organization has recommended (amongst more) that treatment should be made more readily available in primary care and that training of mental health

Abbreviations: CBT, Cognitive Behavioral Therapy; GAD-7, Generalized Anxiety Disorder scale-7; GP, General Practitioner; HRQL, Health-related quality of life; NDH, Norwegian Directory of Health; NIPH, The National Institute of Public Health; IAPT, Increasing Access to Psychological Therapies; PHQ-9, Patient Health Questionnaire-9; PMHC, Prompt Mental Health Care; RCT, Randomized Control Trial; sWEMWBS, The Short Warwick Edinburgh Mental Well-Being Scale; TAU, Treatment As Usual; WSAS, Work and Social Adjustment Scale.

* Corresponding author. Department of Health Promotion, Norwegian Institute of Public Health, Zander Kaaes gate 7, 5015, Bergen, Norway.

E-mail addresses: makalani@myrtveit.com (S.M. Myrtveit Sæther), marit.knapstad@fhi.no (M. Knapstad), n.Grey@sussex.ac.uk (N. Grey), marogner@outlook.com (M.A. Rognerud), robert.smith@fhi.no (O.R.F. Smith).

<https://doi.org/10.1016/j.brat.2020.103758>

Received 21 February 2020; Received in revised form 24 September 2020; Accepted 16 October 2020

Available online 20 October 2020

0005-7967/© 2020 Elsevier Ltd. All rights reserved.

professionals should be increased (World Health Organization. The world health report 2001, 2001). In line with this, the program “Improving Access to Psychological Therapies” (IAPT) was initiated in England (NHS Digital, 2018). IAPT is a free of charge, low-threshold service providing stepped-care psychological treatment following the NICE guidelines, with cognitive behavioural therapy (CBT) as the main treatment approach (Clark, 2018; NHS Digital, 2018). The program is considered a rare example of a health-care system successfully scaling up evidence-based practice for common mental disorders (Thornicroft, 2018). It has been established all across England and more than a million people are seen each a year (Clark, 2018; NHS Digital, 2018).

Also in Norway, the mental health treatment gap is estimated to be high (Torvik et al., 2018). The OECD has urged Norway to address this weakness in care provision, with a particular focus on treatment of clients with mild to moderate anxiety and depression (OECD, 2014). An adapted version of IAPT, “Prompt Mental Health Care” (PMHC, “Rask Psykisk Helsehjelp” in Norwegian), was initiated by The Norwegian Ministry of Health and Care Services as a pilot project in 2012 (Norwegian Directorate of health, 2013; Smith, Alves, & Knapstad, 2016). Like IAPT, PMHC offers low-threshold access to evidence-based treatment for anxiety and depression. Clients can contact the service directly; no referral from health personnel is required. The treatment offered is CBT. By using brief treatment and “low-intensity treatments”, such as guided self-help and group courses, the service aims to offer the least intervention necessary for clients, which reduces therapist time per client and enables treatment of more clients (Norwegian Directorate of health, 2013; Smith et al., 2016).

Scaling up treatment for anxiety and depression is expected to give solid return on investment (Chisholm et al., 2016). However, increased treatment provision does not always result in decreased prevalence of anxiety and depression (Jorm, Patten, Brugha, & Mojtabai, 2017). Potential explanations for this could be suboptimal quality of treatment, or treatment not reaching those in greatest need (Jorm et al., 2017). Further, individuals experiencing depression or anxiety can experience relapse after treatment, as well as multiple episodes (Bruce et al., 2005; Bircusa & Iacono, 2007; Hollon, Thase, & Markowitz, 2002). Though CBT is known to be effective for depression and anxiety (Craske et al., 2017; Cuijpers et al., 2013; Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012; Hofmann & Smits, 2008; Otte, 2011; Twomey, O’Reilly, & Byrne, 2015; Zhang et al., 2018), short-term care might not always be enough to sustain improvement over time (Clark, Goodman, & Petitti, 2018; Hollon et al., 2002; Vittengl, Clark, Dunn, & Jarrett, 2007). Programs aiming at alleviating anxiety and depression should therefore be thoroughly evaluated – also after end of care.

Both IAPT and PMHC have been evaluated using single-group pre-post designs and benchmark methodology, with promising results. IAPT was first tested at two demonstration sites, Doncaster and Newham. Both sites achieved good recovery rates (55–56%) (Clark et al., 2009; Parry et al., 2011). After the national rollout, the program has been continuously monitored and annual reports are published by the NHS (NHS digital, 2019). The average recovery rate in 2017/2018 was 50.8% (NHS Digital, 2018). Evaluation of the first 12 PMHC pilot sites gave comparable results, with recovery rates at 65% (missing data handled with multiple imputation) (Knapstad, Nordgreen, & Smith, 2018).

However, symptom trajectory beyond final treatment has seldom been reported, and the lack of systematic follow-up routines is mentioned as one of the current limitations in IAPT (Clark, 2018). Related to the initial evaluation of the two IAPT demonstration sites, a follow-up survey was sent to a subgroup of clients at least four months after treatment termination (Clark et al., 2009). Recovery rates were found to be 42% at follow-up compared to 57% at post-treatment in Newham ($n = 60$), and 50% at follow-up compared to 56% at post-treatment in Doncaster ($n = 452$) (Clark et al., 2009). This indicates that treatment gains at least in part are maintained beyond final treatment. In Norway, this has been confirmed; Improvement in symptoms of anxiety and depression, as well as functional status, observed at

post-treatment in the PMHC pilot was in large maintained at 12 months post-treatment (Knapstad, Sæther, Hensing, & Smith, 2020). Further, recovery rates decreased only slightly from 49.5% at post-treatment to 45.0% at 12 months post-treatment (Sæther, Knapstad, Grey, & Smith, 2019).

However, these short- and long-term findings are based on single-group pre-post methodology. Such studies are prone to selection bias (Ellenberg, 1994), and clients in the IAPT/PMHC samples might not be fully comparable to benchmark samples derived from previous trials. As such, these designs cannot be used to accurately determine whether the observed gains are attributable to the treatments provided.

To counter the uncertainty from existing evaluations, we have conducted the first randomized controlled trial (RCT) of an IAPT-like treatment model. In two PMHC pilot sites (Kristiansand and Sandnes), PMHC treatment was compared to treatment as usual (TAU). The recently published initial evaluation of this RCT shows that the reliable recovery rate six months after baseline was 58.5% in the PMHC group and 31.9% in the TAU group. This gives a between-group effect size of 0.61 (95% CI 0.37 to 0.85, $p < 0.001$). PMHC also resulted in improved functional status, health-related quality of life and mental well-being, whereas the effect on work participation remained inconclusive (Knapstad, Lervik, Sæther, Aarø, & Smith, 2020). For PMHC to be truly effective, these effects should also hold at long-term follow-up.

Against this background, we aimed to investigate how symptoms of anxiety and depression, as well as work participation, functional status, health-related quality of life and mental wellbeing compared between the PMHC and TAU groups at 12 months follow-up.

2. Materials and method

The description of trial design, study setting, recruitment and randomization was first presented in the primary evaluation of the RCT (M. Knapstad, Lervik, Sæther, Aarø, & Smith, 2020) and are summarized in the following.

2.1. Ethical consent and trial registration

The trial was reported according to the CONSORT statement and is registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT03238872). No changes to the design were made after trial commencement. The trial protocol was approved by the Regional ethics committee for Western Norway (REK-vest no. 2015/885).

2.2. Study setting

The National Institute of Public Health (NIPH) was responsible for the study design and data collection. The trial was conducted within routine care at, and in close collaboration with, two PMHC sites; Kristiansand and Sandnes.

These PMHC sites received establishing grants for a four year period (2013–2017) from the Norwegian Directorate of Health and opened for ordinary intake in the autumn of 2014, following a period of establishment, recruitment and education of the team workers. Both teams started with four full time equivalents clinical staff. One clinical psychologist carried the professional responsibility. All workers had a minimum of three years of relevant higher education and completed a one-year mandatory CBT training (M. Knapstad, Lervik, et al., 2020).

2.3. Recruitment and inclusion/exclusion criteria

All GPs in the catchment areas received information about the trial through a letter from the NIPH, as well as directly from the service providers at local GP association meetings. Information about the trial was also provided on the municipality web pages and in local newspapers and radio.

To be eligible for PMHC service during the trial period, the client had

to present with anxiety and/or mild to moderate depression, be 18 years of age or older, live in one of the pilot site municipalities and have basic Norwegian language proficiency. Clients were excluded (from study and from the PMHC service) if they were entitled to secondary health care services due to eating disorder, displayed significant suicide risk, or had a history of bipolar disorder, severe depression, incapacitating anxiety (qualitative consideration on whether client would be able to take part in treatment as offered in PMHC), psychotic symptoms, severe substance abuse, or personality disorder. Clients who had had two or more previous treatment attempts in secondary care services without effect or had serious physical health problem as the main problem were also excluded from the service during the trial period. The former criterion was regarded as an indication of having more severe mental health problems than is targeted in PMHC. Excluded clients were referred to their GP or other relevant services. The eligibility criteria resembled ordinary routines as far as possible. Similar to IAPT, the Patient Health Questionnaire (PHQ-9) and the Generalized Anxiety Disorder scale (GAD-7) were used as screening instruments. Due to the pragmatic nature of the trial, the established cut-offs of PHQ-9 \geq 10 and/or GAD-7 \geq 8 were not used as absolute inclusion criteria for trial participation, but were employed as a guideline as part of an overall assessment during ordinary service. As described in the trial registration (NCT03238872), these cut-offs were used as absolute criteria for the purpose of primary and secondary outcome analyses. It should be noted that previously conducted full sample analyses including those not at caseness at baseline did not substantially alter the main findings for outcomes at 6-month follow-up (M. Knapstad, Lervik, et al., 2020). The language requirement was added for practical purposes, though according to the site personnel resembled ordinary service.

Clients contacting PMHC in Sandnes and Kristiansand got an appointment for individual assessment and clinical interview at the PMHC clinic. The relevance and severity of the mental health problems, as well as client resources and motivation for treatment, were assessed. The clients received information about the study and the PMHC treatment, as well as comprehensive information about the rationale for randomization. In consultation with the client, inclusion/exclusion was decided.

Clients who agreed to participate gave written consent and were asked to register to a secure online data-portal. This portal was specifically developed for the evaluation of PMHC by the Norwegian Social Science Data Services (NSD), and was used for administrative purposes, to randomize eligible clients and to collect all questionnaire data from both clients and therapists.

2.4. Randomization

A randomized controlled superiority design with parallel assignment was used. The participants were randomized (using a computerized random number generator) on a 70:30 ratio (PMHC vs. TAU) with simple randomization within each of the two sites and no further constraints. This ratio made PMHC available to as many clients as possible while still ensuring a control group of sufficient size.

Participants were randomized following completion of the baseline questionnaire. The integrated allocation application secured full allocation concealment. Participants assigned to PMHC were informed about allocation by a member of the PMHC team. Participants assigned to TAU were informed through a standardized letter sent by the project coordinator. The nature of the intervention precluded participants and therapists from being blinded to treatment.

2.5. The intervention

The PMHC intervention, as used in this trial, is also described in previous publications (M. Knapstad, Lervik, et al., 2020; Lervik, Knapstad, & Smith, 2020). A description of key characteristics follows.

2.5.1. PMHC

In PMHC, CBT treatment is offered in both low intensity (guided self-help, psycho-educational courses) and high intensity (individual treatment) forms (Norwegian Directorate of health, 2013; Sæther et al., 2019). The care is organized according to a type of matched-care model, in which information from the initial assessment and client preferences is used to determine the choice of treatment (M. Knapstad, Lervik, et al., 2020; Lervik et al., 2020). This indicates, different from a pure stepped-care approach, that the client does not necessarily start care at the lowest treatment level. However, in order to make treatment available to as many as possible, the Norwegian Directorate of Health recommends low-intensity treatments as the first choice. Individual treatment are framed to 2–15 sessions (Norwegian Directorate of health, 2013). At both trial sites most clients start with a four-session psycho-educational course. This varies, however, based on both the clients' needs and the practical timing of courses. Thus, some may in parallel follow group courses and individual sessions and some may initially have individual sessions and "step down" to follow a group course, e.g. when the client is ready or a group course is starting up. Guided self-help programs were to a little extent readily available during most of the trial period, besides paper-based programs developed by other PMHC centres and some self-help resources. Due to the pragmatic nature of the trial, no extra resources were added or amendments of treatments delivered during the trial. All therapists received regular clinical supervision.

2.5.2. TAU

Treatment as usual included all ordinary services available to the target population. In Sandnes and Kristiansand, as many Norwegian municipalities, this usually included follow-up by the GP, alternatively by private psychologists or occupational health services. The letter informing TAU clients about their allocation, also encouraged clients to contact their GP for further follow-up, and provided references to publicly available self-help resources (internet, books).

2.5.3. Implementation and fidelity evaluation

PMHC, as implemented in this RCT, seemed to reach the intended target group (adults suffering from anxiety disorders and/or mild to moderate depression) (Lervik et al., 2020). The service could also be considered to be low-threshold, as waiting times for care were relatively short (27 days, IQR 18–39), there were no waiting lists, and self-referral was often used (33.3%).

As reported in the primary evaluation (M. Knapstad, Lervik, et al., 2020), the PMHC group received a median of 5 (IQR = 4–9) treatment sessions. In total 85.8% received at least two treatment sessions (assessment not included) and 76.9% completed treatment (therapist reporting that treatment goal was fulfilled and/or completed at least six sessions). Group-based psychoeducation was the primary treatment form for 35.1%, individual CBT for 30.0%, and guided self-help for 0.9%. The remaining 34.0% received a combination of these treatment forms (M. Knapstad, Lervik, et al., 2020; Lervik et al., 2020).

In order to enable fidelity evaluation, sessions were routinely recorded. One expert rater and one trained psychology student, both uninvolved in treatment, rated 10 randomly selected individual sessions and 5 randomly selected group courses according therapeutic competence and adherence using the "Cognitive Therapy Adherence and Competence Scale" (CTACS) (Barber, Liese, & Abrams, 2003). The intraclass correlation was 0.82 (derived from a two-way mixed effects model), indicating excellent agreement between raters (Cicchetti, 1994).

The CTACS scale consists of 25 items measuring adherence (0 "none" to 6 "thorough") and 25 items measuring competence (0 "poor" to 6 "excellent"). Items considered less relevant in the PMHC setting were excluded (details in M. Knapstad, Lervik, et al., 2020). Sufficient fidelity was defined as a mean CTACS score $>$ 3 (Nordgreen et al., 2016). The mean CTACS score (competence and adherence together) was 2.8 (SD = 0.7) for the individual sessions and 3.5 (SD = 0.3) for the group sessions,

suggesting fidelity in the sufficient range, but with obvious room for improvement (M. Knapstad, Lervik, et al., 2020).

Therapists were overall found to be highly motivated, and clients reported high treatment satisfaction. However, the integrated work-focus in treatment was found to be low, as was collaboration with other services, such as GPs, clients work place or social services (Lervik et al., 2020).

2.5.4. Data collection

Data from measurements at baseline, 3 months, 6 months, and 12 months after baseline in both the PMHC- and TAU-group were used for the present study. Participants were invited to fill out questionnaires through standardized e-mails with direct, secure links to the online questionnaires (for all questionnaires apart from those provided under treatment). The questionnaires were largely completed electronically, but in a few cases paper versions were used. One email-reminder per round was used. In the beginning of the trial, a telephone reminder was also used. Due to insufficient specification in the project application, the telephone reminder was replaced by a standardized SMS from March 2017. Clients in the TAU group received gift cards for filling out follow-up questionnaires (up to 50 USD for completing all follow-up questionnaires). Therapists filled out questionnaires concerning the treatment process per case in the PMHC group.

2.6. Outcome variables

In line with the primary evaluation of this RCT (M. Knapstad, Lervik, et al., 2020), the primary outcomes evaluated were symptoms of depression and anxiety, this time at 12 months follow-up. Mean levels of depression and anxiety were investigated, along with (reliable) recovery rates (details below). The secondary outcomes were work participation, mental wellbeing, health-related quality of life and functional status at 12 months follow-up.

2.6.1. Primary outcome variables

2.6.1.1. Symptoms of depression (PHQ-9). Symptoms of depression were measured using the Patient Health Questionnaire (PHQ-9), tapping frequency of nine symptoms (“not at all” (0) to “nearly every day” (3)) the last two weeks (Kroenke, Spitzer, & Williams, 2001; Kroenke, Spitzer, Williams, & Löwe, 2010). A sum score ranging from 0 to 27 was created. The PHQ-9 has been shown to have good psychometric properties (Kroenke et al., 2001) and the Cronbach’s alpha for the instrument was 0.80 in our sample.

2.6.1.2. Symptoms of anxiety (GAD-7). Symptoms of anxiety were measured using the General Anxiety Disorder-7 (GAD-7), including seven items with similar frequency ratings and time frame as PHQ-9 (Kroenke et al., 2010; Spitzer, Kroenke, Williams, & Löwe, 2006). A sum score ranging from 0 to 21 was created. GAD has displayed good reliability and validity for measuring generalized anxiety disorder (Spitzer et al., 2006) and satisfactory sensitivity and specificity for generalized anxiety and other anxiety disorders (Kroenke et al., 2007). In our sample, the Cronbach’s alpha for GAD-7 was 0.83.

2.6.1.3. Recovery rate and reliable recovery rate. Paralleling the evaluations of IAPT (NHS digital, 2019), recovery was defined as scoring above caseness threshold on the PHQ-9 or GAD-7 sum scores at the start of treatment and below caseness threshold on both measures at follow-up. As previously (Knapstad et al., 2018; Smith, Knapstad, Alves, & Aarø, 2017), the caseness thresholds used were ≥ 10 for PHQ-9 and/or ≥ 8 for GAD-7. To account for measurement error, and aligning with the procedures employed for the IAPT evaluations (Clark et al., 2009), reliable recovery rates were also calculated. Using the standard deviation of the sample and Cronbach’s alpha for PHQ and GAD, a change

score of ≥ 6 was derived for PHQ and ≥ 5 for GAD. A client was defined as reliably recovered when scoring below threshold on both measures at follow-up and showing reliable improvement on either PHQ or GAD.

2.6.2. Secondary outcome variables

2.6.2.1. Functional status (WSAS). Functional status was measured using the Work and Social Adjustment Scale (WSAS) (Mundt, Marks, Shear, & Greist, 2002). The WSAS contains 5-items, assessing impairment due to mental health problems during the last month in five domains (0 = not impaired to 8 = severely impaired). The WSAS has been employed in previous evaluations of PMHC (Smith et al., 2016) and IAPT (Clark et al., 2009). In this context, WSAS was found to have discriminant validity to, and comparable reliability and sensitivity to change as, the PHQ-9 and GAD-7 (Zahra et al., 2014).

2.6.2.2. Health-related quality of life (EQ-5D). Health-related quality of life (HRQL) was measured using the EQ-5D (Rabin & Charro, 2001). The paper version was largely completed electronically; a dedicated digital version of the EQ-5D was not used. A simple sum score (5 to 25) was created, where a higher scores indicate poorer HRQL. HRQL as measured by the EQ-5D has been found strongly associated with depression among primary care clients, and to improve when depression is treated (Sobocki et al., 2007).

2.6.2.3. Mental wellbeing (sWEMWBS). The Short Warwick Edinburgh Mental Well-Being Scale (sWEMWBS (Tennant et al., 2007)) was used to measure mental wellbeing. The scale contains 7 items measured on a scale ranging from 1 (“none of the time”) to 5 (“all the time”), with higher scores indicating high levels of positive mental well-being. The psychometric properties of the scale are satisfactory (Bartram, Sinclair, & Baldwin, 2013; Stewart-Brown et al., 2011), also in the PMHC setting (Smith, Alves, Knapstad, Haug, & Aarø, 2017).

2.6.2.4. Work participation. Based on one multi-response item about current work status and one multi-response item about sources of income (together items included information on full-time or part-time work, sick-pay, disability pension, education/training, serving in military, unemployment, homemaking, retirement and more), we determined whether participants were working (full or part time) and not receiving benefits, or not (coded as a binary variable).

2.7. Statistical analyses

2.7.1. Power and sample size

The recovery rate (PHQ-9 score < 10 and GAD-7 score < 8) at 6 months was assumed to be 50% in the PMHC group and 30% in the TAU group (6 months after baseline was time-point chosen for main outcome evaluation). The assumptions were based on the target recovery rate for IAPT and recovery rates in similar control groups from other trials (M. Knapstad, Lervik, et al., 2020). With allocation ratio of 0.7/0.3, alpha set to 0.05, and power of 0.80, the required number of participants would be 155 in the PMHC group and 67 in the TAU group. Allowing for 20% attrition rate at 6 months follow-up, and in order to increase power for sub-group analyses, a sample size of 1108 was aimed for. Recruitment ended in August 2017, primarily as the funding of the centres from the Norwegian Directorate of Health ended in December 2017, and further local funding remained unclarified. By this time, the sample size was not fully reached, mainly due to periods of varying inflow of clients and capacity at both sites due to sick leaves, maternity leave, and turnover.

2.7.2. Main analyses

Paralleling the method used in the primary evaluation, but this time extended to also include the 12 months follow-up data, multiple imputation was used to estimate (reliable) recovery rates at 6 and 12 months

follow-up. First, 200 datasets containing 10 variables (PHQ at 4 time points (baseline, 3, 6 and 12 months follow-up), GAD at 4 time points (as for PHQ), site, and group) were created using Bayesian analysis (MCMC algorithm). Secondly, (reliable) recovery was conditioned on site and group using robust maximum likelihood. (Reliable) recovery rates were derived by treatment group based on model estimates. By applying the formula $d = \ln(OR) * \sqrt{3}$ (Polanin & Snilstveit, 2016), the odds-ratio (OR) of the treatment effect was transformed to a d-family effect size. The numbers needed to treat (NNT) were also calculated.

To examine relapse rates at 12-months follow-up, we included clients

that started treatment with case-level depression and/or anxiety symptoms who were reliably recovered at 6-month follow-up, and completed PHQ-9 and GAD-7 at 12-months follow-up (N = 165). To be counted as a relapse event, symptom scores at 12-months follow-up for at least one of the outcome measures were (1) above level for caseness and were (2) ≥ 6 (PHQ-9) or ≥ 5 (GAD-7) points greater than the symptom scores at 6-months follow-up. A similar definition was used in previous study examining relapse rates in IAPT (Ali et al., 2017).

To examine the specific effects of PMHC on depression and anxiety, the continuous outcome scores of PHQ and GAD were modelled by

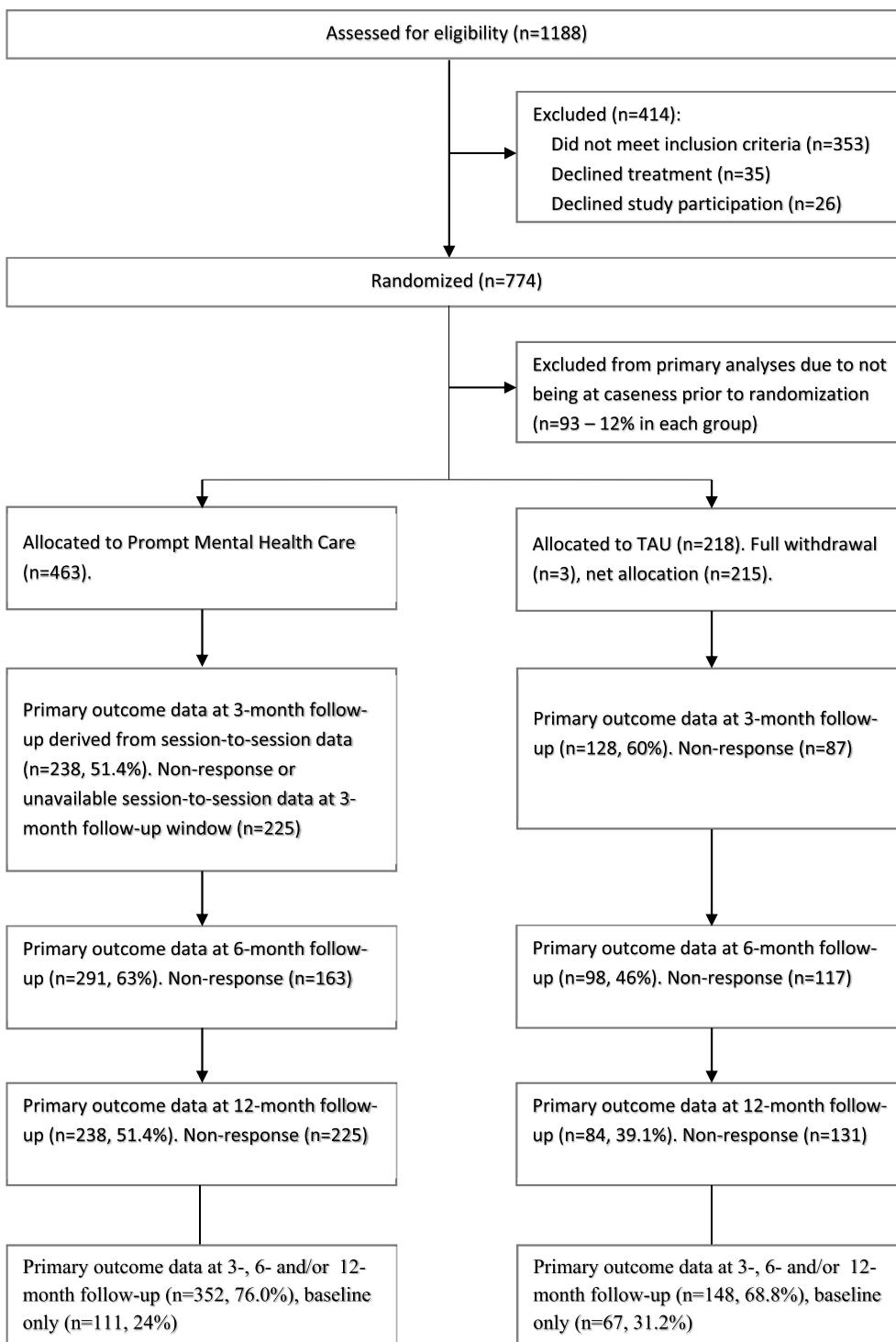


Fig. 1. Flow diagram of PMHC for the period between November 2015 and September 2018.

means of piecewise growth models, in which fixed slopes were estimated for the periods baseline to 3 months, 3 months–6 months, and 6 months–12 months. In these models, only clients with clinically significant scores in the respective scale at baseline were included (≥ 10 for PHQ, $N = 616$; ≥ 8 for GAD, $N = 492$). Site (Kristiansand vs Sandnes) and group (PMHC vs TAU) were included as fixed effects in all models. Between-group effect sizes (d) were calculated by dividing the mean difference in estimated change scores from baseline to 12 months follow-up by the standard deviation at baseline (effect size estimates using the pooled standard deviation can be obtained upon request). Robust maximum likelihood, providing unbiased estimates under the assumption of data missing at random (MAR) (Enders, 2010), was used as estimator.

For work participation, functional status, health-related quality of life and mental well-being, piecewise growth models similar to those presented above were applied. For all outcome analyses, the intention-to-treat principle was applied. It should be noted that the estimates at 6 months follow-up reported in the present study differ slightly from those reported earlier (M. Knapstad, Lervik, et al., 2020), due to the inclusion of data collected at 12 months follow-up.

Data was prepared in, and descriptive analyses performed using, SPSS v.24 and Stata v.15. The main analyses were conducted using Mplus version 8.2.

3. Results

3.1. Participants

As described before (M. Knapstad, Lervik, et al., 2020), and detailed in Fig. 1, 1188 clients were assessed for eligibility between Nov 9, 2015, and Aug 31, 2017. Of these, 774 (92.7% of eligible) were randomized, 26 declined trial participation, 35 declined treatment. Subsequently, 93 participants were excluded from the primary analyses, as they were not above caseness prior to randomization. In total, 463 (68.0%) clients were allocated to PMHC and 218 (32.0%) to TAU. From the TAU group three participants requested full withdrawal, yielding a net allocation of 215 to TAU.

Data collection for the 6 and 12 months follow-ups were finalized by March 2018 and September 2018, respectively. At 12-months follow-up, more data on primary outcomes was available in the PMHC (51.4%, $n = 238$) as compared to the TAU group (39.1%, $n = 84$). Overall, data at follow-up (3, 6, and/or 12 months) was available for 76.0% of the PMHC group and 68.8% of TAU group (see Fig. 1). Missing data on PHQ at 12 months was associated with age (older age; less missing, OR (95%CI): 0.97 (0.96 to 0.98), $p < 0.001$), marital status (alone; more missing, OR (95%CI): 1.56 (1.15 to 2.12), $p = 0.005$) and PHQ score at baseline (higher score; more missing, OR (95%CI): 1.05 (1.01 to 1.08), $p = 0.009$). Missing data on GAD at 12 months was associated with age (older age; less missing, OR (95%CI): 0.97 (0.96 to 0.98), $p < 0.001$), marital status (alone; more missing, OR (95%CI): 1.53 (1.12 to 2.08), $p = 0.007$), and PHQ score at baseline (higher score; more missing, OR (95%CI): 1.05 (1.01 to 1.09), $p = 0.007$). Missing data on PHQ or GAD at 12 months was unassociated with gender, immigration status, education and GAD scores at baseline. PHQ and GAD scores at 12 months were only weakly associated with age and marital status ($r < 0.2$) and with PHQ and GAD scores at baseline ($r < 0.3$). Correlations between PHQ and GAD scores at 12 months and scores at 3 and 6 months were, however, higher ($0.47 < r < 0.67$).

The baseline demographic and clinical characteristics were described in detail in the primary evaluation of the RCT (M. Knapstad, Lervik, et al., 2020) and these data are shown in Table 1. As expected, due to randomization, demographic and clinical characteristics at baseline were similar across the two treatment groups. Overall, two thirds of participants were women and the mean age was 34 years ($SD = 12.2$ SD). Over 40% had higher education, almost 40% were in regular work, and more than half had a partner.

Table 1

Baseline characteristics by treatment group. The descriptive statistics represent percentages (numbers) unless stated otherwise.

Characteristics at baseline	Prompt mental health care (n = 463)	Treatment as usual (n = 215)	Total (n = 678)
Mean (SD) 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, Mean (SD)	14.9 (4.3)	15.0 (4.3)	14.9 (4.4)
Depression, PHQ-9 ≥ 10	90.1 (417)	92.6 (199)	90.9 (616)
Anxiety severity, Mean (SD)	12.1 (4.2)	11.9 (4.2)	12.0 (4.2)
Anxiety, GAD-7 ≥ 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)

Upon inclusion, 90.9% and 87.0% scored above clinical cut-offs for PHQ-9 and GAD-7, respectively. The mean severity scores of PHQ-9 were 14.9 ($SD = 4.4$) and GAD-7 were 12.0 ($SD = 4.2$). Most participants (87.3%) reported having had elevated symptoms at least six months prior to baseline, while 21.9% had sought help for similar problems during the last 12 months.

In the PMHC group, provisional diagnoses were set by the therapists. In total, 38.3% of PMHC participants were reported to have depression, 19.2% to have anxiety and 42.6% to have mixed anxiety and depression. Provisional diagnoses were not set in the TAU group.

3.2. Exposure to treatment outside of PMHC after 12 months since baseline

PMHC: At 12 months follow-up, 25.0% of respondents in the PMHC group reported to have received help for their mental health problems from other services since inclusion in PMHC. In more detail, 10.1% of the respondents received help from their GP without additional specialist care from a psychologist or psychiatrist, 8.4% received help from both, and 3.2% received specialist care without additional help from their GP. That is, 11.6% of the PMHC respondents received additional specialist mental health care. The remaining 3.3% received help from other services at the municipality level.

It should be noted that at 12-month follow-up, 10.5% of the PMHC clients reported to have received additional treatment at PMHC after termination of the main treatment. Based on reports from therapists, this mostly concerned so-called booster sessions.

TAU: At 12 months follow-up, 49.5% of respondents in the TAU group reported having received help for mental health problems from other services since baseline. Here, 5.4% of the respondents received

help from their GP without additional specialist care from a psychologist or psychiatrist, 35.5% received help from both, and 6.5% received specialist care without additional help from their GP. That is, 42.0% of the TAU respondents received specialist mental health care. The remaining 2.1% received help from other services at the municipality level.

3.3. Primary outcomes

3.3.1. (Reliable) recovery rates at 6 and 12 months

Recovery rates and reliable recovery rates in the PMHC and the TAU group are visualized in Fig. 2. At 12 months follow-up, the recovery rate was 64.2% (95% CI 58.5% to 69.8%) in the PMHC group, and 44.9% (95% CI 35.6% to 54.2%) in the TAU group, giving a between-group effect size in favour of the PMHC group of 0.43 (95% CI 0.18 to 0.69, $p < 0.001$). At 6 months, the recovery rate was 62.9% (95% CI 57.5% to 68.1%) in the PMHC group, and 37.4% (95% CI 29.0% to 45.9%) in the TAU group. This gave a between-group effect size in favour of the PMHC group of 0.58 (95% CI 0.34 to 0.82, $p < 0.001$). No evidence was found that the effect of the intervention changed between 6 and 12 months follow-up ($z = 0.98$, $p = 0.32$).

The reliable recovery rate at 12 months was 59.4% (95% CI 53.6 to 65.2) in PMHC and 36.6 (95% CI 27.6 to 45.6) in the TAU group, giving a between-group effect size of 0.51 (95%CI 0.26 to 0.77, $p < 0.001$). At 6 months, the reliable recovery rates was 57.8 (95% CI 52.4 to 63.1) in the PMHC group, and 30.79 (95% CI 22.7 to 38.9) in the TAU group, giving a between-group effect size in favour of PMHC of 0.62 (95%CI 0.38 to 0.87, $p < 0.001$). Again, no evidence was found that the effect of the intervention changed between 6 and 12 months follow-up ($z = 0.56$, $p = 0.45$).

NNT at six months were 3.99 (95% CI 2.35 to 5.65) based on the recovery rates estimates, and 3.76 (95% CI 2.33 to 5.19) based on the reliable recovery rates estimates. At 12 months, NNT were 5.43 (95% CI 1.68 to 9.19) based on the recovery rates estimates, and 4.52 (95% CI 2.13 to 6.91) based on the reliable recovery rates estimates. Thus, the NNT was slightly lower for reliable recovery rate than recovery rate, likely due to the fact that reliable recovery was relatively harder to achieve in the TAU group.

Relapse rates were 10.0% (95% CI 5.7 to 14.3) in the PMHC group, and 16.0% (95% CI 8.0 to 28.0) in the TAU group.

3.3.2. Change in symptoms of anxiety and depression from baseline to 3, 6 and 12 months

As shown in the primary evaluation of the RCT (M. Knapstad, Lervik, et al., 2020), PMHC treatment lead to a greater reduction in symptoms of anxiety and depression from baseline to 6 months than TAU. Fig. 3 shows how this improvement in large was maintained to 12 months in both groups, and that the between-group differences remained.

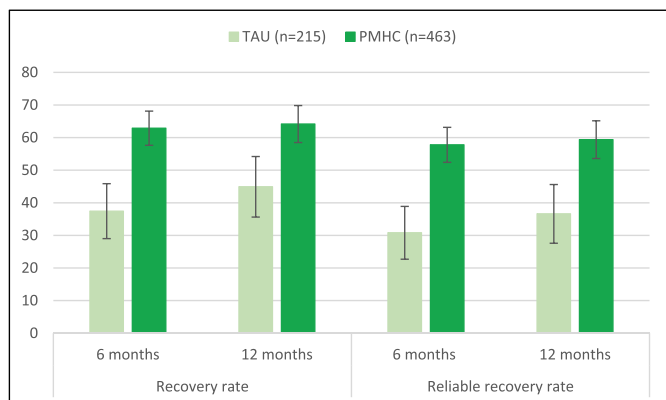


Fig. 2. Recovery rates by treatment group at 6 and 12 months follow-up.

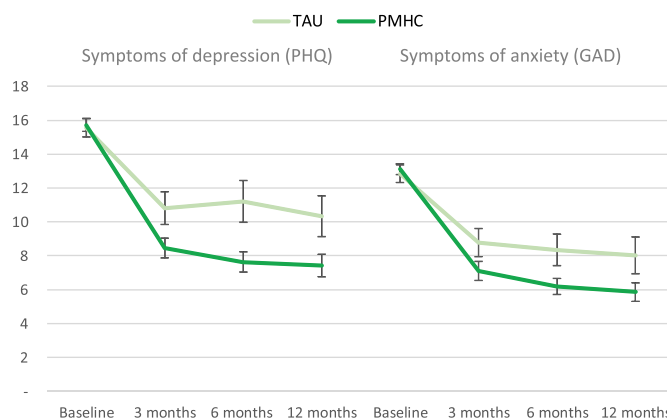


Fig. 3. Change in mean score of symptoms of depression (PHQ) and anxiety (GAD) from baseline to 3, 6 and 12 months.

Symptoms of depression (PHQ): TAU n: 199, PMHC n: 417
Symptoms of anxiety (GAD): TAU n: 187, PMHC n: 403.

At 12 months, the mean score of depressive symptoms was 7.43 (95% CI: 6.76 to 8.10) in the PMHC group and 10.33 (95%CI: 9.13 to 11.54) in TAU. The change in mean levels of depressive symptoms from 6 to 12 months follow-up was not different for PMHC and TAU ($z = 1.00$, $p = 0.32$). At 12 months, the between group effect size was -0.67 (95%CI: -0.99 to -0.36 , $p < 0.001$) in favour of PMHC. 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 ($PHQ \geq 10$, $n = 616$).

The estimated mean levels of anxiety symptoms at 12 months follow-up were 5.92 (95%CI: 4.78–6.37) in PMHC and 8.01 (95%CI: 6.93 to 9.10) in TAU. The change in mean levels of anxiety symptoms from 6 to 12 months follow-up was again not different for PMHC and TAU ($z = -0.004$, $p = 1.00$). At 12 months, the between group effect size was -0.58 (95%CI: -0.91 to -0.26 , $p = 0.001$) in favour of PMHC. 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 ($GAD \geq 8$, $n = 590$).

3.4. Secondary outcomes

Data at 12 months did not give evidence for an effect of PMHC on work participation. At 12 months follow-up, the estimated proportion of participants in full- or part-time regular work was 55.7% in the PMHC group and 58.9% in the TAU group ($z = -0.326$, $p = 0.75$).

As detailed in Table 2, also the improvement in functional status, health related quality of life and positive mental well-being achieved from baseline to three and six months, were in large maintained to 12 months. The between group effect sizes remained substantial and statistically significant for all measures; functional status; -0.42 (95%CI: -0.72 to -0.12), health related quality of life; -0.55 (95%CI: -0.96 to -0.15) and positive mental wellbeing; 0.61 (95%CI: 0.61 to 0.93), all in favour of PMHC. No evidence was found that the change between 6 and 12 months follow-up was different for the PMHC and TAU (all p -values > 0.05).

4. Discussion

4.1. Summary of findings

This study presents the 12 months follow-up data from the first randomized controlled trial of an IAPT-like treatment model. The primary evaluation of the RCT showed substantially larger reduction in symptoms of anxiety and depression from baseline to six months in the PMHC than the TAU group (M. Knapstad, Lervik, et al., 2020). The

Table 2

Change in functional status, health-related quality of life and positive mental wellbeing from baseline to 3, 6 and 12 months.

	Group	Estimated means (95% CI)	Estimated means (95% CI)	Estimated means (95% CI)	Estimated means (95% CI)	Between-group effect size (95% CI)	
		Baseline	3 months	6 months	12 months	12 months	p-value
Functional status	TAU	21.40 (20.32–22.48)		16.03 (14.07–18.00)	15.09 (13.04–17.13)	–0.42 (–0.72–0.12)	0.006
Health-related quality of life	PMHC	21.77 (21.07–22.47)		12.62 (11.05–14.18)	11.66 (10.39–12.94)	–0.55 (–0.96–0.15)	0.008
	TAU	12.21 (11.84–12.57)	10.09 (9.44–10.74)	10.32 (9.54–11.10)	10.01 (9.11–10.91)		
Positive mental wellbeing	PMHC	12.51 (12.25–12.76)	9.01 (8.48–9.55)	8.63 (8.08–9.17)	8.34 (7.74–8.95)	0.61 (0.61–0.93)	<0.001
	TAU	18.54 (18.06–19.03)	20.95 (20.13–21.77)	21.31 (20.30–22.32)	22.05 (20.93–23.16)		
	PMHC	18.38 (18.05–18.7)	22.98 (22.2–23.97)	23.97 (23.23–24.71)	24.66 (23.84–25.48)		

Note: Functional status (WSAS); range of sum-score: 0–40, higher scores indicate more impairment. Health-related quality of life (EQ-5D); range of sum-score: 5 to 25, higher scores indicate poorer health-related quality of life. Mental wellbeing (sWEMWBS); range of sum-score: 7–35, higher scores indicate higher levels of positive mental well-being.

present study adds that, 12 months after baseline, individuals in the PMHC group still reported significantly lower levels of anxiety and depression than individuals in the TAU group. Individuals in the PMHC group also reported better functional status, health-related quality of life and mental wellbeing, and fewer had relapsed than in the TAU group. As loss to follow-up was substantial, the possibility of attrition bias cannot be excluded.

4.2. Interpretation of findings

Though CBT is known to be effective in treating symptoms of depression and anxiety (Craske et al., 2017; Cuijpers et al., 2013; Hofmann et al., 2012; Hofmann & Smits, 2008; Otte, 2011), also in the primary care setting (Twomey et al., 2015; Zhang et al., 2018), the question as to whether short-term treatment models, such as that in PMHC (M. Knapstad, Lervik, et al., 2020) and IAPT (NHS Digital, 2018), are sufficient to sustain improvement over time, has remained. Indeed, relapse after treatment, as well as multiple episodes, are common among individuals experiencing depression or anxiety (Bruce et al., 2005; Bircusa & Iacono, 2007; Hollon et al., 2002). Anxiety disorders are among the most persistent of mental health disorders, with spontaneous remission occurring in less than one in four (Craske et al., 2017). Further, comorbid anxiety and depression seems even more persistent than either anxiety or depression alone (Merikangas et al., 2003).

Against this background, and as over 40% of PMHC clients were given the provisional diagnosis “mixed anxiety and depression” (M. Knapstad, Lervik, et al., 2020) it is particularly uplifting that improvement achieved in the PMHC group is maintained 12 months after baseline. Our findings are in line with a sub-group investigation from IAPT (Clark et al., 2009), as well as findings from the PMHC pilot, indicating that improvement in symptoms (Sæther et al., 2019) lasts beyond final treatment. Importantly, the present study provides novel evidence that a significant part of the maintained improvements at 12 months follow-up can be attributed to the PMHC treatment, due to the inclusion of a comparable control group. Moreover, the relapse rate in the PMHC was only 10%. This was lower than in the TAU group (16%), and far less than the 53% relapse rate observed within 12 months among clients receiving low-intensity treatment in IAPT (Ali et al., 2017). Though results should be interpreted with caution due to risk of attrition bias, these are notable numbers, not least as one in three in PMHC received low-intensity treatment only.

In mental health conditions, symptom reduction constitutes one aspect of recovery, while functional measures seem just as important (McKnight & Kashdan, 2009). This study also adds that functional status, mental well-being and health-related quality of life are also better in the PMHC than the TAU group at 12 months follow-up. Improvement on such measures are central to the estimation of quality-adjusted life years (Sassi, 2006) and the economic evaluation of effectiveness of health care (Sanders, Maciejewski, & Basu, 2019).

In the PMHC pilot investigation, a clear improvement in work status was found, both from baseline to final treatment and from final treatment to 12 months after final treatment (Marit Knapstad, Lervik, et al., 2020). However, when comparing PMHC to TAU six months after baseline, no effect on work participation could be found (M. Knapstad, Lervik, et al., 2020). As changes in function often lag behind improvement in symptoms (Kennedy, Foy, Sherazi, McDonough, & McKeon, 2007; Mintz, Mintz, Arruda, & Hwang, 1992), the six months follow-up in the primary evaluation might have not have been enough to show a meaningful effect. However, neither the current study with 12 months follow-up provided evidence of an effect on work.

Previous research has shown that psychological therapies for common mental disorders, though effective on symptom levels, might not result in improved work participation (Ejebj et al., 2014). Indeed, the relationship between depressive symptoms and functioning seems unexpectedly weak (McKnight & Kashdan, 2009), and symptom relief is associated with only a partial reduction in adverse work outcomes (Adler et al., 2006; Lerner & Henke, 2008). Our findings indicate that if a true effect on work by PMHC does exist, it is likely to be smaller than that on symptoms. As common mental health problems are only one of many factors associated with work participation, this might not be surprising. It should be noted that methodological issues concerning missing data and self-reported work status had a negative impact on statistical power, which limited the possibility to detect smaller effects in the current study.

Even a small effect on work participation could have a large societal, health economic impact (Chisholm et al., 2007). Encouragingly, there is growing evidence that incorporating an explicit work-focus in CBT treatments can improve the effect on work outcomes (Joyce et al., 2016; Nieuwenhuijsen et al., 2014; Reme, Grasdal, Løvvik, Lie, & Øverland, 2015; Øverland, Grasdal, & Reme, 2018), but the picture still is not clear-cut (Salomonsson et al., 2017). Increasing ability to work is one of the main goals of PMHC (Norwegian Directorate of health, 2013). Still, therapists reported that the treatment given during this RCT did not have a high focus on work, and contact between PMHC and the clients' work place was rare (Lervik et al., 2020). Further, even comprehensive work-related interventions might have limited effect if delayed (OECD, 2015). The latter may be of relevance for PMHC, as the majority of clients in our trial reported to have experienced elevated symptoms for at least six months prior to baseline (M. Knapstad, Lervik, et al., 2020). If the focus on work is increased in the further roll-out of PMHC (e.g. a closer collaboration with GPs and work-places and increased use of graded sick leave should be considered), and efforts are made to reach clients earlier, work-related outcomes might improve.

4.3. Strengths and limitations

The main strengths of this study are the use of a randomized controlled study design, reducing the risk of selection bias, and the long

follow-up time, ensuring that effects achieved during treatment are not temporary only. Also, analyses are based on ITT principles. Further, as described in the primary evaluation of the RCT, a strict protocol, including randomization using a computerized random number generator, and a well-powered sample, was followed (M. Knapstad, Lervik, et al., 2020). The procedures followed routine care as closely as possible, and were developed in collaboration with the involved PMHC sites. Validated, reliable instruments, the same as employed within IAPT, were used, making cross-country comparisons of the effectiveness of the services possible.

Though exchangeability holds in well-designed, randomized experiments, estimates might be biased due non-blinding and loss to follow-up (Hernán, 2004). The rate of missing outcome data was both substantial and not equal across treatment groups. This is typical in pragmatic trials in routine care when participants primarily are recruited by seeking treatment, compared to controlled efficacy trials, whereof participants more often are recruited directly to a research project and naturally might be more motivated for participation. Nevertheless, this may have introduced bias that could not be fully mitigated by the state-of-the-art missing data procedures used in this study. For instance, individuals in the TAU group who were disappointed not to have received PMHC, might be more likely not to respond at follow-up, and might have provided more negative scores than non-responders in the TAU group. The results of our study should therefore be interpreted with some caution. However, it should be noted that several sensitivity analyses conducted in the primary evaluation of the RCT indicated that accounting for differential attrition and other missing data not-at-random scenarios did not substantially alter the results (M. Knapstad, Lervik, et al., 2020).

The nature of the treatment made blinding impossible. As described in the primary evaluation (M. Knapstad, Lervik, et al., 2020), the intake assessors were trained to provide a balanced presentation of the treatment alternatives, in order to lower the risk of bias due to knowledge of assignment. GPs were also thoroughly informed about the rationale of the study and randomization process. Still, the lack of blinding might have affected the treatment received in the TAU group, or lead to response bias (Wood et al., 2008), with responses to questionnaires being overly severe in the TAU group and overly optimistic in the PMHC group. However, it seems unlikely that bias due to non-blinding should fully explain the effects observed.

We are currently preparing to link our data to Norwegian registries giving information on use of health services and prescription medication, as well as sick-leave and benefits received. As studies investigating less subjective outcome measures are less prone to response bias (Wood et al., 2008), using register data for such outcomes will be highly valuable. The use of complete registry information will also alleviate some problems due to missing data at follow-up, and will enable us to investigate the impact on work in greater detail and with more statistical power. We further plan to apply the registry data on health care utilization and degree of work participation to perform cost effectiveness and cost utility assessments.

If low-intensity, short-term treatment, as aimed for in PMHC (Norwegian Directorate of health, 2013) and IAPT (NHS Digital, 2018), can lead to lasting improvement in symptoms and function, this can greatly enhance access and cost-effectiveness of care. Previous research indicates that low-intensity treatment forms can be effective in treating anxiety and depression (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Barkowski et al., 2016; Burlingame et al., 2016; Cuijpers, Donker, van Straten, Li, & Andersson, 2010; Cuijpers et al., 2013; Huntley, Araya, & Salisbury, 2012; McDermut, Miller, & Brown, 2001), also in the IAPT (Chan & Adams, 2014) and PMHC (Sæther et al., 2019) setting. However, a recent prospective cohort study investigating IAPT found that 50% of patients having received low-intensity treatment relapsed within the first year (Ali et al., 2017). In the current RCT, only about 1% received guided self-help as primary treatment form (Lervik et al., 2020). Caution is therefore warranted when generalizing the results

from the present study to IAPT-like settings where guided self-help is frequently employed.

Further, TAU included all treatment alternatives available. This pragmatic approach results in complexity and variation of treatment in the TAU group, but was chosen deliberately, in order to reflect of ordinary care and increase external validity.

As anxiety and depression have different courses, and as comorbid anxiety and depression seems even more persistent than either anxiety or depression alone (Merikangas et al., 2003), future research should investigate whether symptom development during and after PMHC differ by presented problems.

Finally, we cannot know for certain whether the choice of excluding individuals who had two or more previous treatment attempts in secondary care services without effect artificially boosted the effectiveness rates of both study arms. We do not know the exact number excluded due to this criterion, but as these treatments took place in secondary services, these clients were more likely to suffer from more severe mental health problems and would therefore be clients outside the PMHC target group. Moreover, previous treatment (by psychologist or psychiatrist the last 12 month) did not predict adjusted pre-post symptom change in the first evaluation of PMHC, where this exclusion criteria was not explicitly employed (Knapstad et al., 2018).

5. Conclusion

The current study shows that PMHC can produce lasting improvement in symptoms, function, mental well-being and health-related quality of life, aspects central to the individual and to the economic evaluation of care. As such, the study provides further evidence that this version of IAPT can be considered a viable supplement to existing health services.

Funding sources

This work was supported by the Norwegian Research Council, [Project number: 260659]. The funding organization did not have any role in study design, data collection, data analysis, data interpretation, or writing of this report, or the decision to publish.

Data availability

The datasets analyzed during the current study are not publicly available due to ethical restrictions and personal data protection, but are available from the corresponding author on reasonable request.

CRediT authorship contribution statement

Solbjørg Makalani Myrtveit Sæther: Conceptualization, Methodology, Formal analysis, Writing - original draft, Writing - review & editing, Visualization. **Marit Knapstad:** Conceptualization, Methodology, Investigation, Writing - review & editing, Project administration, Funding acquisition. **Nick Grey:** Writing - review & editing. **Marit Aase Rognerud:** Writing - review & editing. **Otto R.F. Smith:** Conceptualization, Methodology, Software, Investigation, Resources, Data curation, Formal analysis, Writing - original draft, Writing - review & editing, Supervision, Project administration, Funding acquisition.

Declaration of competing interest

The authors declare no conflicts of interest.

Acknowledgements

We would like to thank the participants for taking part and the PMHC teams in Kristiansand and Sandnes for thorough follow-up of the trial protocol. We would also like to thank the members of the advisory board

- General Hospital Psychiatry, 32(4), 345–359. <https://doi.org/10.1016/j.genhosppsy.2010.03.006>.
- Kroenke, K., Spitzer, R. L., Williams, J. B., Monahan, P. O., & Löwe, B. (2007). Anxiety disorders in primary care: Prevalence, impairment, comorbidity, and detection. *Annals of Internal Medicine*, 146(5), 317–325. <https://doi.org/10.7326/0003-4819-146-5-200703060-00004>.
- Lerner, D., & Henke, R. M. (2008). What does research tell us about depression, job performance, and work productivity? *Journal of Occupational and Environmental Medicine*, 50(4), 401–410. <https://doi.org/10.1097/JOM.0b013e31816bae50>.
- Lervik, L. V., Knapstad, M., & Smith, O. R. F. (2020). Process evaluation of prompt mental health care (PMHC): The Norwegian version of improving access to psychological therapies. *BMC Health Services Research*, 20, 1–17.
- McDermut, W., Miller, I. W., & Brown, R. A. (2001). The efficacy of group psychotherapy for depression: A meta-analysis and review of the empirical research. *Clinical Psychology: Science and Practice*, 8(1), 98–116. <https://doi.org/10.1093/clipsy.8.1.98>.
- McKnight, P. E., & Kashdan, T. B. (2009). The importance of functional impairment to mental health outcomes: A case for reassessing our goals in depression treatment research. *Clinical Psychology Review*, 29(3), 243–259. <https://doi.org/10.1016/j.cpr.2009.01.005>.
- Merikangas, K. R., Zhang, H., Avenevoli, S., Acharyya, S., Neuenschwander, M., & Angst, J. (2003). Longitudinal trajectories of depression and anxiety in a prospective community study: The Zurich cohort study. *Archives of General Psychiatry*, 60(10), 993–1000. <https://doi.org/10.1001/archpsyc.60.9.993>.
- Mintz, J., Mintz, L. I., Arruda, M. J., & Hwang, S. S. (1992). Treatments of depression and the functional capacity to work. *Arch Gen Psychiatry*, 49(10), 761–768. <https://doi.org/10.1001/archpsyc.1992.01820100005001>.
- Mundt, J. C., Marks, I. M., Shear, M. K., & Greist, J. M. (2002). The work and social adjustment scale: A simple measure of impairment in functioning. *The British Journal of Psychiatry*, 180(5), 461–464. <https://doi.org/10.1192/bjp.180.5.461>.
- NHS Digital. (2018). *Psychological therapies: Annual report on the use of IAPT services in England (2017–18)*. Retrieved from Leeds.
- NHS digital. (2019). *Psychological Therapies A guide to IAPT data and publications*. Retrieved from Accessed from <https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/improving-access-to-psychological-therapies-data-set/improving-access-to-psychological-therapies-data-set-reports>.
- Nieuwenhuijsen, K., Faber, B., Verbeek, J. H., Neumeyer-Gromen, A., Hees, H. L., Verhoeven, A. C., ... Bültmann, U. (2014). Interventions to improve return to work in depressed people. *Cochrane Database of Systematic Reviews*, 12. <https://doi.org/10.1002/14651858.CD006237.pub3>.
- Nordgreen, T., Haug, T., Ost, L.-G., Andersson, G., Carlbring, P., Kvale, G., ... Havik, O. E. (2016). Stepped care versus direct face-to-face cognitive behavior therapy for social anxiety disorder and panic disorder: A randomized effectiveness trial. *Behavior Therapy*, 47(2), 166–183. <https://doi.org/10.1016/j.beth.2015.10.004>.
- Norwegian Directorate of health. (2013). *Rask Psykisk Helsehjelp – 12 pilotkommuner. Veiledende materiell*. Oslo: Helsedirektoratet.
- OECD. (2014). *OECD reviews of health care quality: Norway 2014: Raising standards*. Retrieved from Paris <https://www.oecd.org/publications/oecd-reviews-of-health-care-quality-norway-2014-9789264208469-en.htm>.
- OECD. (2015). *Fit mind, fit job. From evidence to practice in mental health and work*. Retrieved from Paris <https://www.oecd.org/els/fit-mind-fit-job-9789264228283-en.htm>.
- Otte, C. (2011). Cognitive behavioral therapy in anxiety disorders: Current state of the evidence. *Dialogues in Clinical Neuroscience*, 13(4), 413.
- Øverland, S., Grasdahl, A. L., & Reme, S. E. (2018). Long-term effects on income and sickness benefits after work-focused cognitive-behavioural therapy and individual job support: A pragmatic, multicentre, randomised controlled trial. *Occupational and Environmental Medicine*, 75, 703–708. <https://doi.org/10.1136/oemed-2018-105137>.
- Parry, G., Barkham, M., Brazier, J., Dent-Brown, K., Hardy, G., Kendrick, T., ... Lovell, K. (2011). *An evaluation of a new service model: Improving access to psychological therapies demonstration sites 2006-2009*. Retrieved from http://www.netscc.ac.uk/hsdr/files/project/SDO_FR_08-1610-154_V01.pdf.
- Polanin, J., & Snijlsteit, B. (2016). Converting between effect sizes. *Campbell Systematic Reviews*, 12(1). <https://doi.org/10.4073/cmpn.2016.3>.
- Rabin, R., & Charro, F.d. (2001). EQ-SD: A measure of health status from the EuroQol group. *Annals of Medicine*, 33(5), 337–343. <https://doi.org/10.3109/07853890109002087>.
- Reme, S. E., Grasdahl, A. L., Løvvik, C., Lie, S. A., & Øverland, S. (2015). Work-focused cognitive-behavioural therapy and individual job support to increase work participation in common mental disorders: A randomised controlled multicentre trial. *Occupational and Environmental Medicine*, 72(10), 745–752. <https://doi.org/10.1136/oemed-2014-102700>.
- Salomonsson, S., Santoft, F., Lindaster, E., Ejeby, K., Ljotsson, B., Ost, L. G., ... Hedman-Lagerlof, E. (2017). Cognitive-behavioural therapy and return-to-work intervention for patients on sick leave due to common mental disorders: A randomised controlled trial. *Occupational and Environmental Medicine*, 74(12), 905–912. <https://doi.org/10.1136/oemed-2017-104342>.
- Sanders, G. D., Maciejewski, M. L., & Basu, A. (2019). Overview of cost-effectiveness analysis. *Journal of the American Medical Association*, 321(14), 1400–1401. <https://doi.org/10.1001/jama.2019.1265>.
- Sassi, F. (2006). Calculating QALYs, comparing QALY and DALY calculations. *Health Policy and Planning*, 21(5), 402–408. <https://doi.org/10.1093/heapol/czl018>.
- Sæther, S. M. M., Knapstad, M., Grey, N., & Smith, O. R. F. (2019). Twelve months post-treatment results from the Norwegian version of improving access to psychological therapies. *Frontiers in Psychology*, 10(2303). <https://doi.org/10.3389/fpsyg.2019.02303>.
- Smith, O. R., Alves, D. E., & Knapstad, M. (2016). *Rask Psykisk Helsehjelp: Evaluering av de første 12 pilotene i Norge. [Prompt Mental Health Care: Evaluation of the first 12 pilot sites in Norway]*. Retrieved from Oslo: <https://www.fhi.no/publ/2016/rask-psykisk-helsehjelp-evaluering-av-de-forste-12-pilotene-i-norge/>.
- Smith, O. R., Alves, D. E., Knapstad, M., Haug, E., & Aarø, L. E. (2017). Measuring mental well-being in Norway: Validation of the warwick-edinburgh mental well-being scale (WEMWBS). *BMC Psychiatry*, 17(1), 182. <https://doi.org/10.1186/s12888-017-1343-x>.
- Smith, O. R., Knapstad, M., Alves, D. E., & Aarø, L. E. (2017). Initial results of prompt mental health care, the Norwegian version of improving access to psychological therapies. *Psychotherapy and Psychosomatics*, 86(6), 382–384. <https://doi.org/10.1159/000477668>.
- Sobocki, P., Ekman, M., Ågren, H., Krakau, I., Runeson, B., Mårtensson, B., et al. (2007). Health-related quality of life measured with EQ-5D in patients treated for depression in primary care. *Value in Health*, 10(2), 153–160. <https://doi.org/10.1111/j.1524-4733.2006.00162.x>.
- Spitzer, R. L., Kroenke, K., Williams, J. B., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: The GAD-7. *Archives of Internal Medicine*, 166(10), 1092–1097. <https://doi.org/10.1001/archinte.166.10.1092>.
- Stewart-Brown, S. L., Platt, S., Tennant, A., Maheswaran, H., Parkinson, J., Weich, S., ... Clarke, A. (2011). The warwick-edinburgh mental well-being scale (WEMWBS): A valid and reliable tool for measuring mental well-being in diverse populations and projects. *Journal of Epidemiology & Community Health*, 65(Suppl 2), A38–A39.
- Tennant, R., Hiller, L., Fishwick, R., Platt, S., Joseph, S., Weich, S., ... Stewart-Brown, S. (2007). The warwick-edinburgh mental well-being scale (WEMWBS): Development and UK validation. *Health and Quality of Life Outcomes*, 5(1), 63. <https://doi.org/10.1186/1477-7525-5-63>.
- Thornicroft, G. (2018). Improving access to psychological therapies in England. *The Lancet*, 391(10121), 636–637. [https://doi.org/10.1016/S0140-6736\(17\)32158-X](https://doi.org/10.1016/S0140-6736(17)32158-X).
- Thornicroft, G., Chatterji, S., Evans-Lacko, S., Gruber, M., Sampson, N., Aguilar-Gaxiola, S., ... Kessler, R. C. (2017). Undertreatment of people with major depressive disorder in 21 countries. *British Journal of Psychiatry*, 210(2), 119–124. <https://doi.org/10.1192/bjp.bp.116.188078>.
- Torvik, F. A., Ystrom, E., Gustavson, K., Rosenström, T. H., Bramness, J. G., Gillespie, N., ... Reichborn-Kjennerud, T. (2018). Diagnostic and genetic overlap of three common mental disorders in structured interviews and health registries. *Acta Psychiatrica Scandinavica*, 137(1), 54–64. <https://doi.org/10.1111/acps.12829>.
- Twomey, C., O'Reilly, G., & Byrne, M. (2015). Effectiveness of cognitive behavioural therapy for anxiety and depression in primary care: A meta-analysis. *Family Practice*, 32(1), 3–15. <https://doi.org/10.1093/fampra/cmu060>.
- Vittengl, J. R., Clark, L. A., Dunn, T. W., & Jarrett, R. B. (2007). Reducing relapse and recurrence in unipolar depression: A comparative meta-analysis of cognitive-behavioral therapy's effects. *Journal of Consulting and Clinical Psychology*, 75(3), 475–488. <https://doi.org/10.1037/0022-006X.75.3.475>.
- Wood, L., Egger, M., Gluud, L. L., Schulz, K. F., Jüni, P., Altman, D. G., ... Sterne, J. A. (2008). Empirical evidence of bias in treatment effect estimates in controlled trials with different interventions and outcomes: meta-epidemiological study. *BMJ*, 336(7644), 601–605.
- World Health Organization, & The world health report 2001. (2001). *Mental health: New understanding, new hope*. Retrieved from Geneva: <http://www.who.int/whr2001/>.
- Zahra, D., Qureshi, A., Henley, W., Taylor, R., Quinn, C., Pooler, J., ... Byng, R. (2014). The work and social adjustment scale: Reliability, sensitivity and value. *International Journal of Psychiatry in Clinical Practice*, 18(2), 131–138. <https://doi.org/10.3109/13651501.2014.894072>.
- Zhang, A., Franklin, C., Jing, S., Bornheimer, L. A., Hai, A. H., Himle, J. A., ... Ji, Q. (2018). The effectiveness of four empirically supported psychotherapies for primary care depression and anxiety: A systematic review and meta-analysis. *Journal of Affective Disorders*. <https://doi.org/10.1016/j.jad.2018.12.008>.