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Social anxiety and agoraphobia symptoms effectively treated by Prompt Mental Health Care versus TAU at 6- and 12-month follow-up: Secondary analysis from a randomized controlled trial

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Abstract

Background: Prompt Mental Health Care (PMHC, Norwegian adaption of Improving Access to Psychological Therapies) has shown effects on symptoms of anxiety and depression compared to treatment as usual (TAU). In this secondary analysis, we examine the effectiveness of PMHC among clients presenting with symptoms of social anxiety disorder (SAD) and/or agoraphobia on core symptoms at 6- and 12-month follow-up.

Methods: Randomized controlled trial in two PMHC sites (70:30 ratio PMHC:TAU). Of participants, 61.3% (n = 472) scored at caseness for SAD and 47.7% (n = 367) for agoraphobia (40% both). Effects on SAD avoidance and physiological discomfort (SPIN-9), SAD cognitions (ATQ-SA), agoraphobic avoidance (MIA-8), and agoraphobic cognitions (ATQ-AP) were examined in piecewise growth models.

Results: The PMHC group showed substantially greater symptom reduction than the TAU group for all outcomes: At 6-month follow-up, the between-group effect sizes were d −0.60 (95% CI: −0.94 to −0.26) for SPIN-9, −0.45 (95% CI: −0.70 to −0.20) for ATQ-SA, −0.50 (95% CI: −0.87 to −0.13) for MIA-8, and −0.61 (95% CI: −0.92 to −0.31) for ATQ-AP. All effects were sustained at similar level at a 12-month follow-up.

Conclusion: PMHC effectively alleviated SAD and agoraphobia symptoms, and individuals struggling with such symptoms constituted a large proportion of clients. Although results should be interpreted with caution due to risk of attrition bias, they lend further support for a scale-up of PMHC and similar initiatives. Individuals struggling with SAD and/or agoraphobia stood out as relatively high burdened, whereas only one of five had sought help the last 12 months, underscoring the need for the PMHC service.

KEYWORDS

agoraphobia, clinical trials, cognitive behavior therapy, primary care, social anxiety disorder

1 | INTRODUCTION

Social anxiety disorder (SAD) and agoraphobia are two of the most common and disabling anxiety disorders. Their large negative impacts are related to high prevalence (Lecrubier et al., 2000; Remes et al., 2016; D. J. Stein et al., 2017) and early onset (Jones, 2018; Kessler et al., 2007), but also by their wide-ranging associated impairment across several life domains, such as sleep, social/romantic relations, and occupational life (Aderka et al., 2012; Fehm et al., 2008; Lecrubier et al., 2000; M. B. Stein & Kean, 2000; D. J. Stein et al., 2017; Stuhldreher et al., 2014; Wittchen & Beloch, 1996), seen both in diagnostic threshold and subthreshold cases (Fehm et al., 2008). Moreover, both are associated with an elevated risk of developing other disorders, such as depression and alcohol/substance dependence (Lecrubier et al., 2000) and to follow a chronic course if left untreated (Bruce et al., 2005; Steinert et al., 2013; Wittchen & Beloch, 1996). Agoraphobia often occurs comorbid to panic disorder (Goisman et al., 1995), and these were conceptually linked in DSM-IV whilst are coded separately in DSM-5 (Center for Behavioral Health Statistics and Quality, 2016). Despite their massive costs, both for the individual and society, anxiety disorders are often undetected in primary care (Kroenke et al., 2007) if at all seen, as individuals with SAD, in particular, tend to avoid seeking help (Lecrubier et al., 2000).

Prompt Mental Health Care (PMHC) is the Norwegian adaptation of the English "Increasing Access to Psychological Therapies" (IAPT), both innovative initiatives to improve access to primary care treatment for persons with symptoms of mild-to-moderate depression and anxiety disorders, including SAD and agoraphobia. Key features to enable large-scale roll-out and ensure broad and prompt access (in PMHC within 48 h), are the offering of more low-intensity treatments (guided self-help and psycho-educative courses) and training of new therapists (1-year training). PMHC treatments are based on cognitive-behavioral therapy (CBT). The service should supplement existing services, be free of charge, and without need for referral (see Lervik et al., 2020 for more details).

Although IAPT and PMHC were evaluated positively in several studies (Knapstad et al., 2018; Myrtveit et al., 2019), one common critique was that the available evidence was not based on studies using a randomized controlled trial (RCT) design. Both among researchers and policymakers, the idea persists that people with mild-to-moderate anxiety and depression may not need treatment (D. M. Clark et al., 2009; Shepardson et al., 2018). These aspects were important reasons for conducting an RCT in Norway, comparing PMHC to treatment as usual (TAU). Primary and secondary outcomes from this trial are previously reported, finding PMHC more effective than TAU (Knapstad et al., 2020), including sustained effects at 12-month follow-up (Sæther et al., 2020). The treatment effect for individuals struggling with specific anxiety problems, such as social anxiety or agoraphobia, is yet to be addressed. The single group evaluation of the 12 first PMHC pilots promisingly showed medium to large pre-post improvement in symptoms of both SAD (SPIN-9, $d = -0.6$) and agoraphobia (MIA-8, $d = -0.8$). These findings are, however, hampered by the lack of a control group and a modest participation rate (overall 65%). Long-term effects are also unknown.

CBT is considered to be the first-line treatment for both SAD and agoraphobia (Bandelow et al., 2015; Carpenter et al., 2018; Hans & Hiller, 2013; Hofmann et al., 2012; Mayo-Wilson et al., 2014). Treatment effects and magnitude of effects are, however, still uncertain. First, only a few high-quality trials have been conducted and these show lower effect sizes than low-quality studies for both SAD and agoraphobia (Cuijpers et al., 2016). Second, most trials have used waitlist control groups, which also gain higher effect sizes than other control modes (Cuijpers et al., 2016). In sum, Cuijpers et al. (2016) did not find enough high-quality studies to evaluate the effect of CBT compared to TAU for SAD in a 2016 review. Additionally, some evidence indicate that treatment effects are somewhat lower for SAD and panic disorder with agoraphobia than many other anxiety disorders (Carpenter et al., 2018) and agoraphobic avoidance is found to be the most consistent predictor of poor treatment response in CBT for panic disorders and agoraphobia (Porter & Chambless, 2015). Notably, also in an IAPT context, presenting with SAD or agoraphobia as a comorbid problem predicted poor treatment response (McDevitt-Petrovic et al., 2019).

The objective in the current study is thus to do secondary analyses of the PMHC trial to investigate the effectiveness of the PMHC treatment compared to TAU among clients presenting with symptoms of SAD and/or agoraphobia on core symptoms at 6- and 12-month follow-up. More specifically, the outcomes of interest are SAD avoidance and physiological discomfort, SAD cognitions, agoraphobic avoidance, and agoraphobic cognitions. We will also examine the characteristics of clients presenting with symptoms of SAD and/or agoraphobia as compared to PMHC clients in total.

2 | MATERIALS AND METHODS

The trial was reported according to the CONSORT statement and is registered at 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). The outcomes in the present study (social anxiety, agoraphobia) were not preregistered in the trial protocol. Details about the trial design are provided in the primary evaluation (Knapstad et al., 2020) and summarized in the following.

2.1 | Recruitment and selection procedures

The trial was conducted within routine care in two municipalities; Kristiansand and Sandnes. Eligibility criteria were anxiety and/or mild-to-moderate depression (PHQ-9 ≥ 10 and/or GAD-7 ≥ 8, no formal diagnosis provided), being ≥18 years old, residing in Kristiansand or Sandnes, and having basic Norwegian language proficiency. Clients were excluded if they were entitled to

secondary healthcare due to suicide risk, eating disorder, bipolar disorder, severe depression, incapacitating anxiety, psychotic symptoms, severe substance abuse, or personality disorder. Additional exclusion criteria during the trial were having a serious physical health problem or two or more previous treatment attempts without effect. Excluded clients were referred to their GP or other relevant services.

Those contacting PMHC in Sandnes and Kristiansand got an appointment for individual assessment at the PMHC clinic. A therapist conducted a clinical interview, provided information about the trial and PMHC treatment. Eligible clients agreeing to participate gave written consent and registered to a secure online data-portal used for administrative purposes, to randomize eligible clients, and to collect all questionnaire data from both clients and therapists.

2.2 | Trial design and 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. Participants allocated to PMHC were informed by a member of the PMHC team, whilst the TAU group were informed through a standardized letter sent by the project coordinator.

2.3 | Interventions

A summary of interventions follows, we refer to the primary evaluation for further details (Knapstad et al., 2020; Lervik et al., 2020).

2.3.1 | Prompt Mental Health Care

A matched-care model organized care, where both initial assessment and client preferences informed choice of treatment, notably with low-intensity treatments as recommended first choice. At both trial sites, most clients started with a four-session psychoeducational course. Guided self-help programs were to a little extent readily available during most of the trial period. Individual CBT was framed to 2–15 sessions. Treatment type and length did not differ significantly between those scoring above and below the clinical threshold for SAD/agoraphobia (all $p > .05$). The whole PMHC group received median 5 (IQR = 4–9) treatment sessions. In total, 85.8% received at least two treatment sessions (ex. assessment) 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.

2.3.2 | Treatment as usual

This included all ordinary services available to the target population. This often 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).

As previously reported (Sæther et al., 2020), about one in four reported at a 12-month follow-up to have received some form of additional treatment in the PMHC group since baseline, while this was one in two in the TAU group. The additional treatment was mainly provided by GP's and/or specialist mental healthcare (Sæther et al., 2020). These patterns were similar for the subgroups of clients with clinically significant baseline levels of social anxiety and agoraphobia. As such, the TAU condition reflected, as intended, the situation before the arrival of PMHC.

2.4 | Measures

In the present study, we used data collected at baseline, 3, 6, and 12 months after baseline in both the PMHC and TAU groups.

2.4.1 | SAD avoidance and physiological discomfort

An abbreviated form of the widely used Social Phobia Inventory (Connor et al., 2000), SPIN-9, was employed, whereof five items regard avoidance (e.g., being in the center of attention, going to parties) and four physiological discomfort (e.g., blushing, trembling). Responses were given on a five-point scale ("not at all" (1) to "extremely" (5) bothered the past week).

2.4.2 | Agoraphobic avoidance

We used an abbreviated version of the Mobile Inventory for Agoraphobia (Chambless et al., 1985), MI-9, suggested from generalizability study carried out at Modum bad (Hoffart et al., 2018). The clients rated avoidance due to anxiety or discomfort of nine places/situations, both when alone and when accompanied by a trusted companion, on a five-point scale ranging from "never" (1) to "always" (5).

2.4.3 | SAD cognitions and agoraphobic cognitions

We employed items from the Anxious Thoughts Questionnaire (ATQ) relating to social anxiety (ATQ-SA) and agoraphobia (ATQ-AP). ATQ-SA contains four items from the social probability and cost questionnaire (McManus et al., 2000), selected on the basis of their high Cronbach's α (Hoffart et al., 2009). ATQ-AP contains three items concerning physical catastrophes and four

concerning loss of control catastrophes from the agoraphobic cognitions questionnaire (Chambless et al., 1984), selected based on Cronbach's α and frequent endorsement in a study among patients considering agoraphobia their main problem (Hoffart, 1995). Responses were given on a scale from 0 (not at all agree) to 100 (totally agree), recoded to 1–11, giving a sum score of 4–44 for ATQ-SA 7-77 for ATQ-AP.

2.5 | Analyses

Stata version 15 was used to generate descriptive statistics. To examine the effects of PMHC on the SAD and agoraphobia outcomes, their continuous scores were modeled by means of piecewise growth models in Mplus v. 8.2, in which fixed slopes were estimated for the intervals baseline to 6 months, and baseline to 12 months. For the SAD outcomes, only clients with clinically significant levels of SAD were included as defined by a SPIN-9 score more than 18 ($N = 472$; Connor et al., 2000; IAPT Data Handbook, 2011). For the agoraphobia outcomes, only clients with clinically significant levels of agoraphobia were included as defined by an MI-9 score ≥1.61 ($N = 367$; Chambless et al., 2011). Site (Kristiansand vs. Sandnes) and group (PHMC 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 6- and 12-month follow-up by the standard deviation at baseline. Robust maximum likelihood was used as an estimator, providing unbiased estimates under the assumption of data missing at random (Enders, 2010).

3 | RESULTS

3.1 | Participant flow and baseline data

As previously described (Knapstad et al., 2020), 1188 clients were assessed for eligibility between November 9, 2015 and August 31, 2017. Of these, 774 (92.7% of eligible) were randomized, 26 declined trial participation, 35 treatment. In total, 526 (68.0%) clients were allocated to PMHC and 248 (32.0%) to TAU. Four TAU participants requested full withdrawal, giving a net allocation of 244 to TAU. As shown in the primary evaluation, demographic and clinical characteristics were balanced between the groups at baseline (Knapstad et al., 2020).

Of the participants, 61.3% ($n = 321$ in PMHC and $n = 151$ in TAU) scored at caseness SAD and 47.7% ($n = 247$ in PMHC and $n = 120$ in TAU) for agoraphobia at baseline. There was a substantial overlap between these groups; 65.3% of the SAD cases also scored at caseness for agoraphobia, and 83.9% vice versa (40% both). The correlation between the outcome measures was moderate to strong (Table 1). However, there was a maximum of 40.1% overlap between variables (SPIN-9 and ATO-SA), clearly indicating that they measured separate constructs.

TABLE 1 Correlation (Pearson's r) between continuous outcomes at baseline

	SPIN-9	MIA-8	ATQ-SA	ATQ-AP
SPIN-9	1.00			
MIA-8	0.54	1.00		
ATQ-SA	0.64	0.39	1.00	
ATQ-AP	0.40	0.39	0.58	1.00

Note: All correlations significant at $a\ p < .001$ level.
Abbreviations: ATQ-AP, Anxious Thoughts Questionnaire−Agoraphobia; ATQ-SA, Anxious Thoughts Questionnaire-Social Anxiety; MIA-8, Mobile Inventory for Agoraphobia-8; SPIN-9, Social Phobia Inventory-9.

Table 2 displays baseline demographic and clinical characteristics of the total sample and participants scoring at caseness for SAD and agoraphobia, respectively. There were several statistically significant differences between clients above and below clinical cutoff, albeit of small magnitude. For both the SAD and agoraphobia groups, the following characteristics stood out: fewer had higher education and were in regular work, and they had a higher mean score of symptoms of anxiety (GAD-7) and depression (PHQ-9; Table 2). The agoraphobia group also included a higher percentage of women than the remaining clients.

3.2 | Outcomes

Data collections for 6- and 12-month follow-up were finalized by March 2018 and September 2018, respectively. Slightly more outcome data were available in the PMHC than the TAU group (60 vs. 45% data available at 6 months and 51 vs. 39% at 12 months). We refer to the main outcome papers for a detailed evaluation of loss to follow-up (Knapstad et al., 2020; Sæther et al., 2020). Shortly, missing data were associated with some individual characteristics, such as age and baseline PHQ score, though with modest effect sizes. The correlations between outcome and these variables were mostly weak, which reduced the possibility to correct for bias in case of missing not at random.

Overall, the PMHC group showed substantially more symptom reduction than the TAU group between baseline and 6-month follow-up for all four outcomes. Furthermore, symptom levels remained rather stable from 6 to 12 months as did between-group effect sizes at 12-month follow-up for all outcomes. Symptom score changes and between-groups effect sizes per outcome are detailed in Table 3.

3.2.1 | Change in SAD avoidance and physiological symptoms (SPIN-9) and SAD cognitions (ATQ-SA) from baseline to 6 and 12 months

Among those scoring at caseness for SAD according to SPIN-9 ($n = 472$), the estimated SPIN score changed from 26.48 at baseline

TABLE 2 Baseline characteristics of total PMHC trial sample and clients scoring at caseness for social anxiety disorder (SAD) and agoraphobia

Characteristics at baseline	PMHC trial sample in total (*n* = 770)	Social anxiety disorder[a] (*n* = 472)	Agoraphobia[a] (*n* = 367)
Mean (*SD*) age (years)	35.0 (12.2)	34.0 (12.2)**	33.9 (12.7)*
Women	66.0 (508)	67.2 (317)	73.8 (271)***
Higher education	42.5 (324)	34.3 (160)***	31.6 (115)***
Having a partner	57.3 (438)	54.4 (254)*	52.6 (191)*
Being in regular work	37.5 (289)	31.8 (150)***	30.3 (111)***
Immigration background	11.1 (85)	11.3 (53)	11.2 (41)
Anxiety severity, Mean GAD score (*SD*)	11.2 (4.6)	12.2 (4.3)***	12.5 (4.2)***
Depression severity, Mean PHQ score (*SD*)	13.9 (5.0)	15.1 (4.8)***	15.2 (4.9)***
Weekly use of anxiolytic medication	6.1 (47)	6.7 (31)	7.4 (27)
Daily use of antidepressants	13.6 (104)	16.0 (75)*	16.0 (58)
Weekly use of sleep medication	15.0 (115)	17.7 (83)**	16.3 (59)
Having elevated symptoms ≥6 months before baseline	86.9 (667)	88.8 (419)*	89.4 (328)*
Having symptoms at baseline level ≥6 months before baseline	65.6 (499)	69.3 (322)**	70.3 (255)*
Sought help for similar problems during the last 12 months before baseline	20.8 (160)	21.2 (100)	22.1 (81)

Note: The descriptive statistics represent percentages (numbers) unless stated otherwise, cases are compared to noncases. *$p < .05$, **$p < .01$, ***$p < .001$. Abbreviations: GAD, generalized anxiety disorder; PHQ, Patient Health Questionnaire; PMHC, Prompt Mental Health Care; SD, standard deviation.
[a]Differences between clients above and below clinical cutoff compared using χ^2 tests and two-sample *t* tests.

to 19.84 at 6 months in the PMHC group, and 26.94 to 23.10 in TAU (Table 3). This equaled a between-group effect size of *d* −0.60 (95% CI: −0.94 to −0.26, *p* = .001). The change from 6 to 12 months did not differ between PMHC and TAU (Wald test: 0.087, *df* = 1, *p* = .768), and the between-group effect size of change from baseline to 12-month follow-up was *d* −0.55 (95%CI: −0.95 to −0.14, *p* = .008).

For SAD cognitions, there was a mean score difference at 6-month follow-up of −5.24 (95%CI: −8.17 to −2.31) and a between-group effect size of −0.45 (95% CI: −0.70 to −0.20, *p* < .001), both in favor of PMHC (Table 3). At 12 months, the mean difference remained similar at −5.74 (95% CI: −9.03 to −2.46) and the between-group effect size was −0.49 (95% CI: −0.77 to −0.21, *p* = .001). Again, there was no difference in change in symptoms from 6 to 12 months between PMHC and TAU (Wald test: 0.124, *df* = 1, *p* = .725).

3.2.2 | Change in agoraphobic avoidance (MIA-8) and agoraphobic cognitions (ATQ-AP) from baseline to 6 and 12 months

Among those scoring above the clinical threshold for agoraphobia (*n* = 367), the estimated MIA-8 score changed from 41.68 at baseline to 29.95 at 6 months in PMHC and 42.70–35.74 in TAU, giving a between-group Cohen's *d* of −0.50 (95% CI: −0.87 to −0.13, *p* = .008). In both groups, the symptom level remained rather stable from 6 to 12 months, with no difference in degree of change (Wald test: 0.429, *df* = 1, *p* = .513). The between-group effect size at 12 months was −0.62 (95% CI: −0.98 to −0.26, *p* = .001; Table 3).

Finally, the estimated agoraphobic cognitions score changed from 26.64 at baseline to 15.83 at 6 months in PMHC and 26.69–25.00 in TAU, giving a between-group effect size of −0.61 (95% CI: −0.92 to −0.31, *p* < .001). The change from 6 to 12 months follow-up did not differ between PMHC and TAU (Wald test: 0.00, *df* = 1, *p* = .991), and between-group effect size at 12 months remained at −0.61 (95% CI: −0.93 to −0.30, *p* < .001).

4 | DISCUSSION

4.1 | Main findings

In this pragmatic RCT trial of PMHC, 61.3% of clients had clinical levels of SAD and 47.7% agoraphobia at baseline (40% both). Among these, the PMHC treatment group showed substantially more improvement on core symptoms at both 6- and 12-month follow-up than the TAU group. More specifically, close to medium and medium between-group effect sizes (Cohen's *d* range: −0.45 to −0.61) were found for SAD avoidance and physiological discomfort, SAD catastrophic cognitions, agoraphobic avoidance, and agoraphobic catastrophic cognitions. These treatment effects were sustained and did not change from 6 to 12 months follow-up.

TABLE 3 Change in symptoms of social anxiety (SPIN-9), social anxiety-related cognitions (ATQ-SA), agoraphobic avoidance (MIA-8), and agoraphobic cognitions (ATQ-AP) from baseline to 6 and 12 months

	Group	Estimated means (95% CI) Baseline	Estimated means (95% CI) 6 months	Estimated means (95% CI) 12 months	Between-group effect size (95% CI) 6 months	*p*	Between-group effect size (95% CI) 12 months	*p*
Symptoms of social anxiety (SPIN-9; *n* = 472)	TAU	26.94 (26.15–27.74)	23.10 (21.52–24.69)	22.22 (20.31–24.13)				
	PMHC	26.48 (25.89–27.06)	19.84 (18.86–20.82)	19.24 (18.12–20.36)	0.60 (−0.94 to −0.26)	.001	0.55 (−0.95 to −0.14)	.008
Social anxiety cognitions (ATQ-SA; *n* = 472)	TAU	24.39 (22.66–26.12)	20.04 (17.46–22.61)	20.34 (17.37–23.31)				
	PMHC	24.08 (22.86–25.29)	14.80 (13.39–16.22)	14.59 (13.14–16.05)	−0.45 (−0.70 to −0.20)	<.001	−0.49 (−0.77 to −0.21)	.001
Agoraphobic avoidance (MIA-8; *n* = 367)	TAU	42.70 (40.52–44.88)	35.74 (32.02–39.45)	34.90 (31.15–38.65)				
	PMHC	41.68 (40.39–42.98)	29.95 (27.98–31.93)	27.74 (25.83–29.65)	−0.50 (−0.87 to −0.13)	.008	−0.62 (−0.98 to −0.26)	.001
Agoraphobic cognitions (ATQ-AP; *n* = 367)	TAU	26.69 (24.14–29.23)	25.00 (20.73–29.26)	23.96 (19.44–28.47)				
	PMHC	26.64 (24.90–28.38)	15.83 (14.01–17.65)	14.81 (13.09–16.54)	−0.61 (−0.92 to −0.31)	<.001	−0.61 (−0.93 to −0.30)	<.001

Note: SPIN-9; range of sum-score: 9–45, higher scores indicate more symptoms of social anxiety. ATQ_SA; range of sum-score: 4–44, higher scores indicate more social anxiety-related cognitions. MI-8; range of sum-score: 18–90, higher scores indicate more agoraphobic avoidance behavior. ATQ_AP; range of sum-score: 7–77, higher scores indicate more agoraphobic cognitions.

Abbreviations: ATQ-AP, Anxious Thoughts Questionnaire—Agoraphobia; ATQ-SA, Anxious Thoughts Questionnaire-Social Anxiety; MIA-8, Mobile Inventory for Agoraphobia-8; SPIN-9, Social Phobia Inventory-9.

4.2 | Interpretation

The treatment effects found are solid and particularly encouraging in light of the short-term treatment (median 5 sessions) and frequent use of group-based psychoeducation (35% this format only) provided in the PMHC group. As mentioned in Section 1, albeit a range of studies has shown effect of CBT for anxiety disorders, including SAD and agoraphobia, fewer have been conducted in primary care settings and included long-term follow-up. Especially it is questioned whether short-term care is able to sustain improvement over time (A. Clark et al., 2018; Hollon et al., 2002; Vittengl et al., 2007), and the lack of systematic follow-up routines is mentioned as one of the current limitations in IAPT (D. M. Clark, 2018).

The magnitude of effects is comparable to CBT trials for SAD and agoraphobia using TAU control groups, which in meta-analyses are reported to be of small to medium size (Acarturk et al., 2008; Cuijpers et al., 2016). A meta-analysis of multimodal CBT for anxiety and depression in primary care, thus similar to the PMCH setting, gave a medium effect size ($d = 0.46$) for anxiety symptoms when compared to TAU. Separate results for social anxiety and agoraphobia were, however, not provided, and follow-up time was only a medium of four months. A recent, comprehensive meta-analysis focusing on long-term effects found small to medium effect sizes across control conditions for SAD both between 6 and 12 months (Hedges $g = 0.34$) and ≥12 months follow-up ($g = 0.42$). For panic disorder with or without agoraphobia, however, CBT was only found superior when compared to pill placebo, and only at 6 to 12 months follow-up (van Dis et al., 2020). Notably, as these were studies of patients having received a formal diagnosis, and mostly following traditional face-to-face CBT, the findings are not directly comparable to those from the present study.

Individuals struggling with SAD and/or agoraphobia constituted a large proportion of clients in this trial. This was similarly found in a sample of clients awaiting treatment within an IAPT service, where 48% met criteria for a MINI agoraphobia diagnosis and 22/11% with a generalized/nongeneralized social phobia (Hepgul et al., 2016). Moreover, the socioeconomic characteristics of those above the clinical cutoff in the current trial mirrored epidemiological studies, for instance, finding SAD to be associated with younger age, female gender, and lower education (D. J. Stein et al., 2017). These results may indicate that PMHC succeeds in reaching out to and is well received in this group of clients. This is generally important, as viable scale-up of treatment programs not only depends on offering effective treatment but also reaching those in greatest need (Jorm et al., 2017). For SAD and agoraphobia, this is particularly relevant, as individuals struggling with SAD tend to avoid seeking help or talk about their problems (Lecrubier et al., 2000), and make fewer primary care visits compared to individuals with other mental disorders (Gross et al., 2005). In addition, their problems often go unrecognized in primary care (Kroenke et al., 2007). It can be speculated that services like PMHC, which focus on the normalization of mental health problems, may reduce the threshold of seeking help. Taking efforts to further increase reach out will be valuable both from a cost-perspective and individual burden and quality of life-perspective (Stuhldreher et al., 2014). Notably, the SAD and agoraphobia subgroups displayed moderate-severe mean PHQ9 baseline-scores, possible indicating comorbidity. Comorbidity can be regarded "a rule more than an exception" for these anxiety problems, commonly depression in SAD (Lecrubier et al., 2000) and panic disorder in agoraphobia (Goisman et al., 1995), and is associated with a higher overall burden. As the study was conducted in a real life-primary care setting and included a heterogeneous population, not formally diagnosed, the results might not be specific to SAD/agoraphobia, but more general to individuals experiencing anxious distress and possibly multiple problems or disorders. The implications of the comorbidity between SAD and depression are multiple (Koyuncu et al., 2019), but may most notably affect the course and outcome of treatment. As such, the observed effects on symptoms of SAD can be interpreted as reassuring.

The current NICE guideline recommendation is still to offer individual instead of group CBT in treatment of SAD, pointing to evidence that the latter is less clinical- and cost-effective (National Institute of Health and Care Excellence, 2013). It is thus interesting to observe that psychoeducational group-courses were offered to clients with SAD symptoms to the same extent as other clients in PMHC, and that as many as one in three received this treatment modality only. Psychoeducational groups in PMHC were employed both as a mean to avoid waiting lists and therapeutically to foster normalization of mental health problems. While we do not know to what extent the observed effect of PMHC is driven by group treatment, the findings are encouraging for the acceptability and clinical effectiveness of psychoeducational groups among clients struggling with SAD and agoraphobia. A large network meta-analysis notably found large effects for SAD of both individual and group CBT when compared to wait-list control, but only of individual CBT when compared to psychological controls (Mayo-Wilson et al., 2014). Future studies should investigate how different treatment elements within the context of PMHC (low intensity, high intensity, mixed) contribute individually on symptoms of SAD and agoraphobia.

4.3 | Strengths and limitations

The current study responds well to the call for well-powered RCTs (van Dis et al., 2020; Imai et al., 2016; Porter & Chambless, 2015), including ITT-analyses (Carpenter et al., 2018) and long-term follow-up (van Dis et al., 2020; Imai et al., 2016; Mayo-Wilson et al., 2014). The trial followed a strict protocol to secure control whilst following routine care as closely as possible to maximize external validity. We employed IAPT's recommended measures for SAD (SPIN) and agoraphobia (MI), respectively (D. M. Clark, 2018; National Institute of Health and Care Excellence, 2013), which have solid psychometric properties and facilitated comparisons with IAPT results.

The most important limitation to consider is the loss to follow-up, which is a common challenge in these kinds of studies (van Dis et al., 2020). As the rate of missing outcome data was both

substantial and not equal across treatment groups, this may have introduced bias that could not be fully mitigated by the state-of-the-art missing data procedures used. Notably, modeling of IAPT data showed that clients suffering with agoraphobia were less likely to attend their appointments than those with other anxiety disorders (Firth et al., 2020). In the current trial, such noncompliance could provide bias if differential across the treatment arms. Though bias cannot be fully excluded, several sensitivity analyses conducted in the primary outcome paper indicated that accounting for differential attrition and other missing data not-at-random scenarios did not substantially alter the results (Knapstad et al., 2020).

The additional treatment outside PMHC, reported by about 25% of participants in the PMHC group, may account for some of the reported effectiveness of PMHC versus TAU. However, given the randomization and that the majority did not receive additional treatment, we expect this effect to be relatively small.

It should also be noted no formal diagnoses are set in PMHC and that it is unclear to what extent the PMCH group received treatment specifically for SAD or agoraphobia. The findings might thus be particularly relevant to similar primary care settings.

5 | CONCLUSION

Individuals struggling with SAD and/or agoraphobia constituted a large proportion of clients in this trial, which showed that the PMHC treatment effectively alleviated SAD and agoraphobia symptoms compared to TAU. Their socioeconomic characteristics mirrored the picture from epidemiological studies, indicating that PMHC succeeds in reaching out to and is well received in this group of clients. The current results thus add to previous findings supporting a further scale-up of PMHC to narrow the treatment gap. A scale-up can be considered particularly valuable for individuals struggling with SAD and/or agoraphobia, as they were relatively more burdened than the remaining PMHC clients presented, displaying higher symptom severity and less work participation.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

Both authors contributed to the design of the study, analyses, interpretation of the data, revised the manuscript, and approved the final version to submit for publication. Otto R. F. Smith performed the main analyses. Marit Knapstad drafted the manuscript.

DATA AVAILABILITY STATEMENT

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.

ETHICS STATEMENT

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 primary and secondary outcomes after trial approval. All participants have given their written informed consent.

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