

INTRODUCTION

Panic disorder with or without agoraphobia is found in about 4% of primary care patients¹. Patients show severe impairments in daily functioning and considerable reductions in quality of life. Most of them seek and receive mental health care by general practitioners. However, recognition and treatment in routine primary care settings has been described as sub-optimal². The "Patient Activation for Anxiety Disorders" (Paradise) intervention is a team-supported, self-managed exposure training to be carried out by small, non-specialized practice teams in primary care.

OBJECTIVE

To determine whether a practice-team-supported, self-managed exposure training is superior to usual care in terms of clinical outcomes.

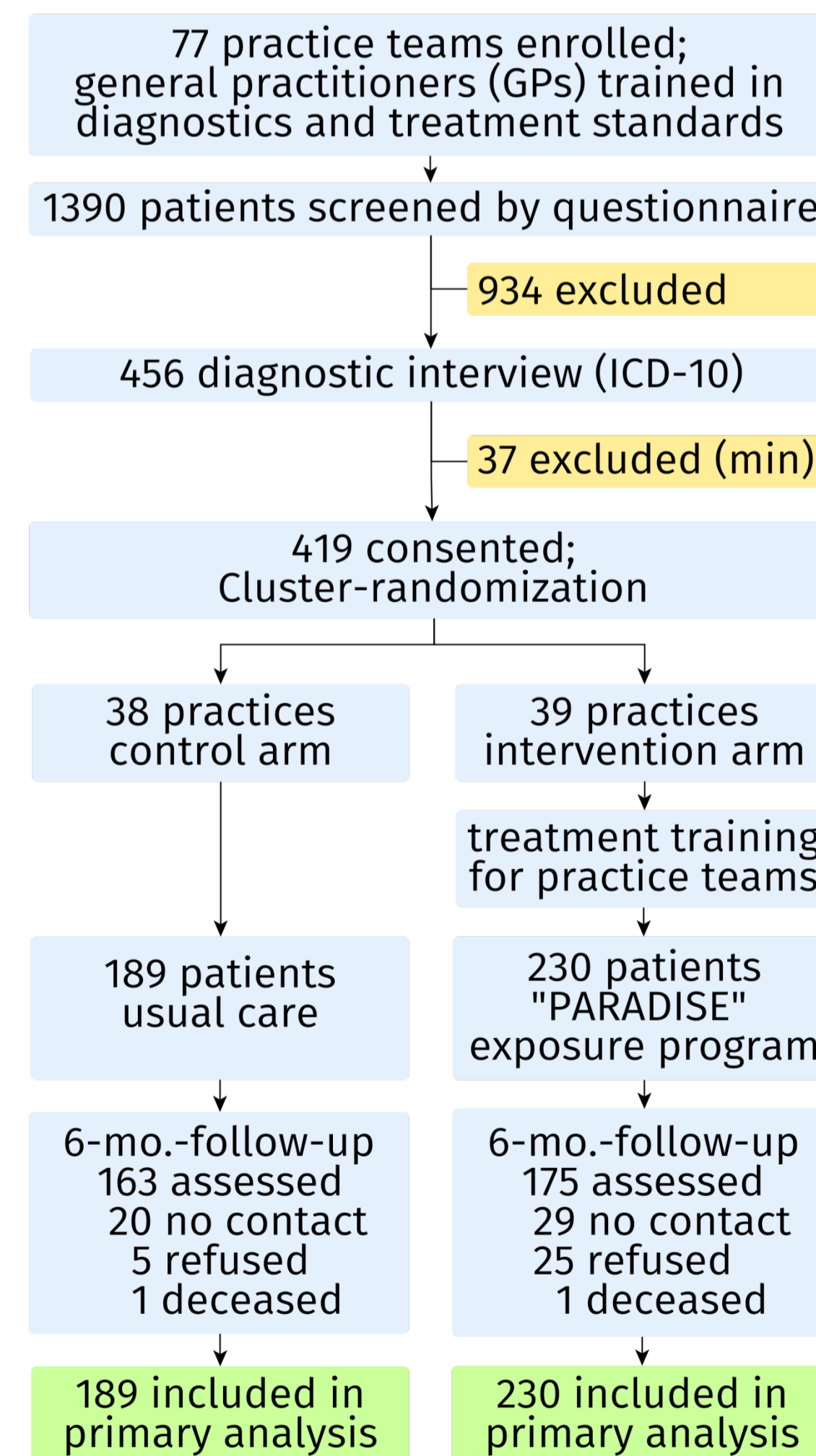


Fig. 1 Flow chart of the trial

METHODS

Design: Cluster-randomized controlled trial with two-arm parallel group design.
Setting: 73 German general practices participating in statutory health care.
Patients: General practitioners recruited adult patients using screening questionnaires and ICD-10 checklists for panic disorder with/without agoraphobia. Exclusion criteria: acute suicidal tendencies; psychotic, addictive, or severe somatic disorders, current psychotherapy for anxiety.
Intervention: In the "Paradise"-intervention group, patients received a self-help manual, 4 structured appointments with the general practitioner who delivered instructions to conduct exposure exercises, and periodical phone calls from a health care assistant who monitored symptoms and encouraged adherence to exposure training. Practice teams attended a 3 h-workshop and received treatment manuals. In the control group, patients received usual care according to recommended treatment standards.
Primary clinical outcome: Severity of anxiety (Beck Anxiety Inventory - BAI).
Data collection: Measures were administered by practice teams at baseline and after interventions (6-month-follow-up).
Analysis: Mixed linear models considering study centers as random and baseline measures as fixed factors will show superior clinical outcomes in "Paradise" as compared to usual care.

	Usual Care (n = 189)	Paradise (n = 230)
Patient Demographic Characteristics		
Age, mean years (SD)	46.3 (14.8)	46.1 (14.1)
Sex, No. female (%)	145 (76.7)	166 (72.2)
Patient clinical features		
Age of first onset of panic disorder, mean (SD)	31.7 (14.3)	32.0 (14.8)
Comorbid agoraphobia, No. (%)	135 (71.4)	180 (78.3)
Anxiety severity and impairment (OASIS), mean (SD)	12.5 (2.8)	12.5 (2.7)
Psychiatric co-treatment, No. (%)	26 (14.9)	26 (12.5)
Practice-level baseline characteristics	(n = 38)	(n = 39)
GP age, mean years (SD)	50.9 (8.2)	52.3 (8.4)
GP sex, No. female (%)	19 (50.0)	18 (46.2)
HCA age, mean years (SD)	36.4 (11.4)	40.4 (10.8)
HCA sex, No. female (%)	38 (100.0)	39 (100.0)
Single-handed practice	23 (60.5)	26 (66.7)
Group practice	15 (39.5)	13 (33.3)
Practice location rural, No. (%)	24 (63.2)	25 (64.1)
urban, No. (%)	14 (36.8)	14 (35.9)

Tab. 1 Baseline Characteristics

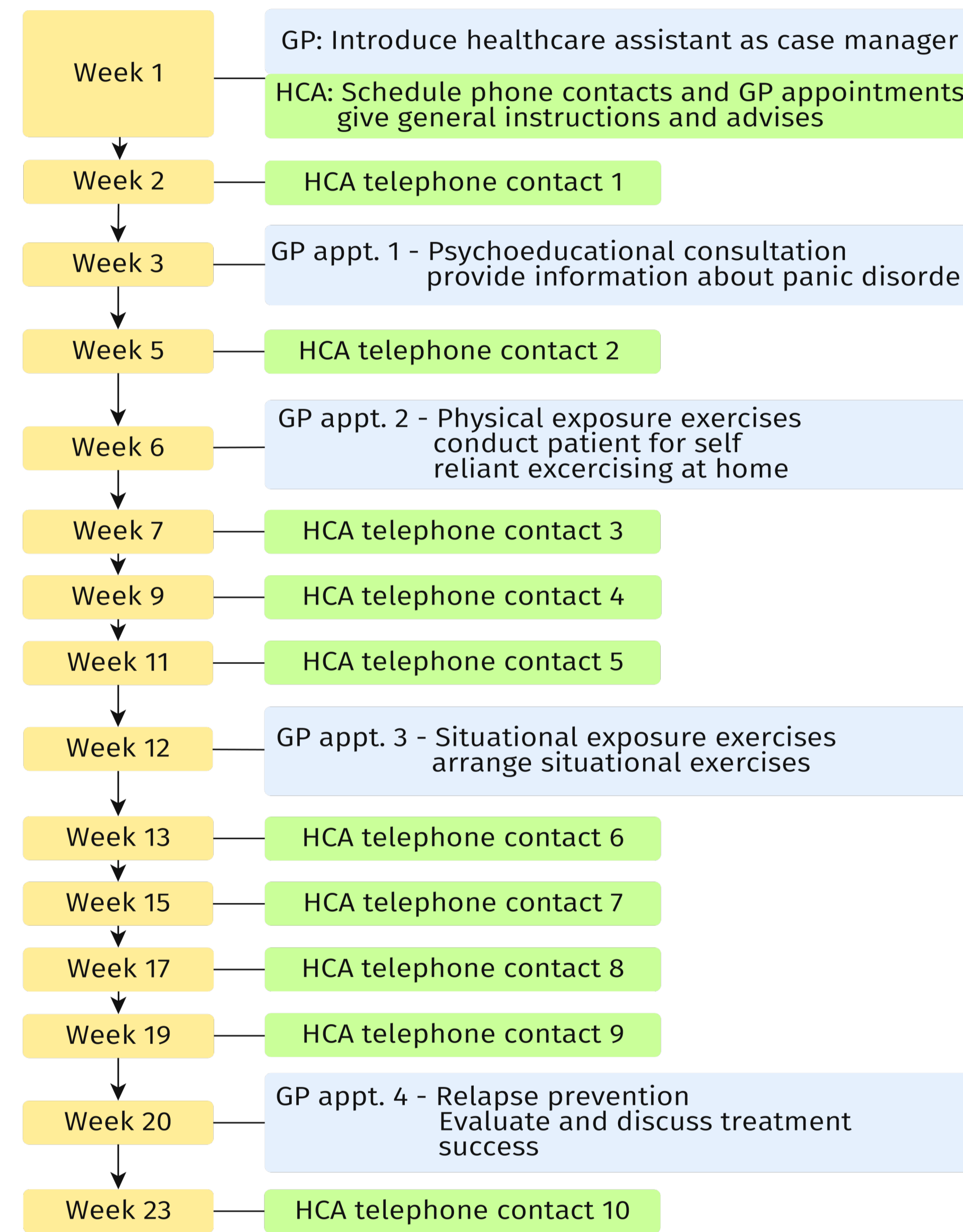


Fig. 2 Treatment schedule with team tasks (GP = general practitioner, HCA = healthcare assistant)

CONCLUSION & CLINICAL IMPLICATIONS

Clinical outcomes for patients with panic disorder and agoraphobia in primary care can be improved by a practice team-supported, self-managed exposure training. The intervention can be applied by general practitioners and health care assistants following a limited interventional training. This may increase the availability of evidence-based, low-threshold treatments for patients with highly prevalent anxiety disorders.

RESULTS

Both groups showed improvements in the primary (Severity of Anxiety - BAI) and secondary (Depression - PHQ-9, Patient Assessment of Chronic Illness Care - PACIC, Mobility Inventory A - MIA) outcomes at post-treatment. Mixed linear models revealed greater changes to baseline in the intervention group as compared to the control group, as indicated by significant group-by-time interactions. With regard to BAI, the intra-cluster correlation (ICC) amounted to 0.03. The dropout rate was 19.3% (control: 13.8%, intervention: 23.9%).

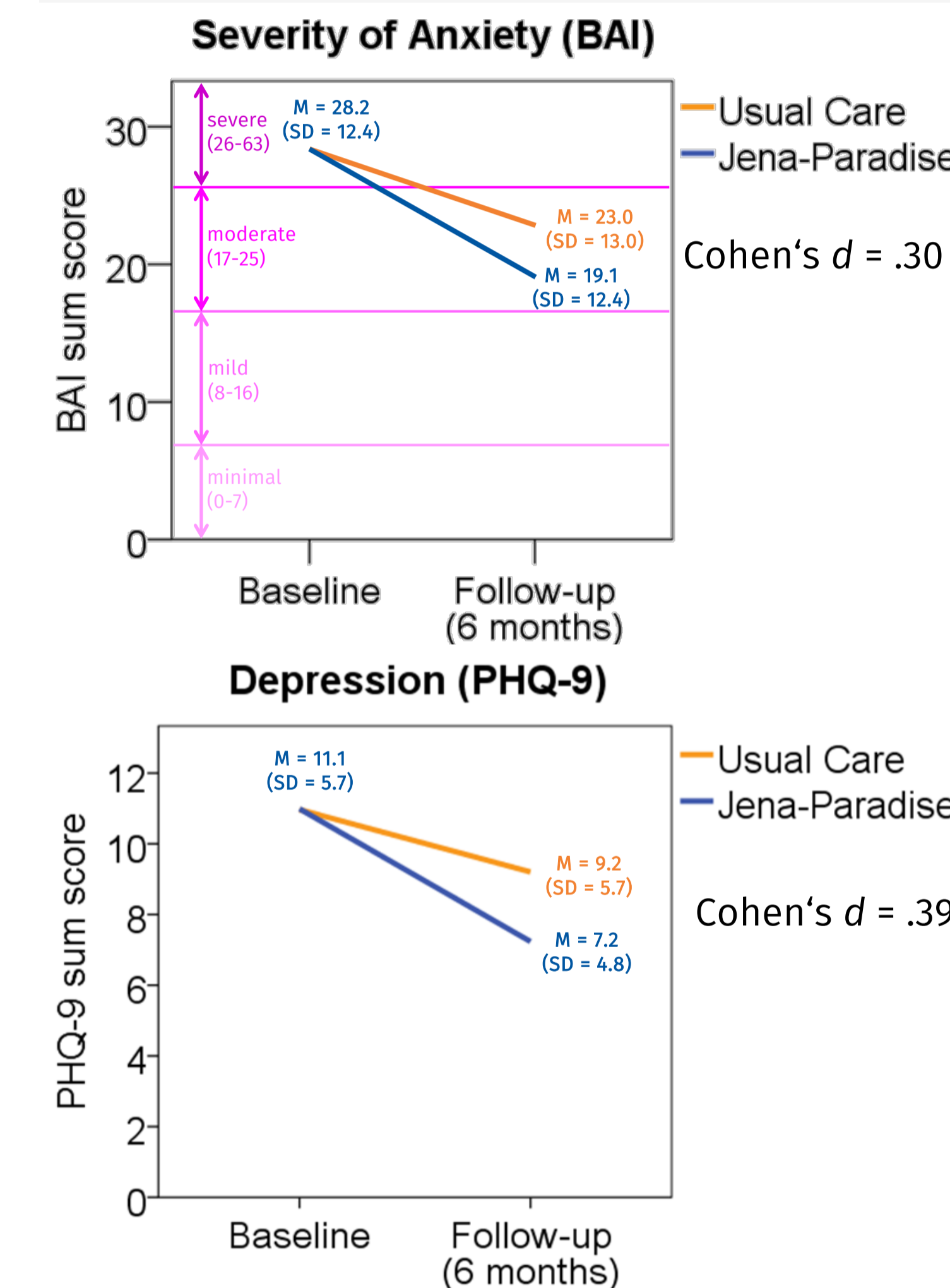


Fig. 3 Outcome of anxiety severity and depression

DISCUSSION

The „Paradise“-intervention integrated evidence-based methods derived from the chronic care model and recommended cognitive-behavioral treatment elements. Clinical efficacy for primary care patients with severe anxiety disorders could be demonstrated. However, dropout was higher in the intervention group than in the control group which may indicate selective application efficacy of „Paradise“ in different patients. Furthermore, long-term efficacy has not been analyzed yet (data collection for 12-months-follow up is currently ongoing).

Mixed Model Analysis of BAI - Estimates of Fixed Effects

Parameter	Estimate	SE	t	df	p
Intercept	27.96	1.27	22.05	70	< .0001
Treatment(Paradise vs. usual care)	0.17	1.35	0.13	309	.8994
Time (follow-up vs. baseline)	-5.20	1.03	-5.03	309	< .0001
Practice (rural vs. urban location)	0.37	1.29	0.28	70	.7772
Treatment * Time	-3.40	1.43	-2.38	309	.0178

Tab. 2 Mixed Model Analysis of BAI

time	Outcome	Control	Intervention	d
T0	N	179	220	
	BAI, mean (SD)	28.2 (12.4)	28.2 (12.5)	
T1	N	156	166	
	BAI, mean (SD)	23 (12.8)	19.1 (11.9)	.31
T0	N	129	164	
	MIA, mean (SD)	2.2 (0.8)	2.2 (0.8)	
T1	N	118	120	
	MIA, mean (SD)	2.2 (0.8)	1.9 (0.8)	.35
T0	N	182	224	
	PHQ, mean (SD)	11.8 (5.9)	11.1 (5.5)	
T1	N	157	171	
	PHQ, mean (SD)	9.2 (5.7)	7.2 (4.8)	.36
T0	N	154	201	
	PACIC, mean (SD)	6.4 (2.7)	6.0 (2.5)	
T1	N	147	160	
	PACIC, mean (SD)	6.5 (2.8)	7.4 (2.5)	.38

Tab. 3 Primary/secondary outcome results

Ref: Löwe B, Gräfe K, Zipfel S, Spitzer RL, Herrmann-Lingen C, Witte S, et al. Detecting panic disorder in medical and psychosomatic outpatients: comparative validation of the hospital anxiety and depression scale, the patient health questionnaire, a screening questionnaire, and physicians' diagnosis. Journal of psychosomatic research. 2003 Dec;55(6):515-9. PubMed PMID: 14642981. PubMed Central PMCID: PMC1171. Epub 2003/12/04. eng.
 2: Perugi G, Frare F, Toni C. Diagnosis and treatment of agoraphobia with panic disorder. CNS Drugs. 2007;21(9):741-64. PubMed PMID: 17696574. Epub 2007/08/19. eng.