

A Telephone- and Text Message-Based Telemedicine Concept for Patients with Mental Health Disorders: Results of a Randomized Controlled Trial

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Key Words

Telemedicine · Telephone-based therapy · Effectiveness of telemedicine treatment · Depression · Anxiety

Abstract

Background: A telemedicine care concept based on telephone contacts and individualized text messages was developed for patients with mental disorders to continue treatment after therapy in a psychiatric day hospital. The primary objective of this study was to evaluate the effectiveness of the telemedicine interventions. **Methods:** The study had a 3-armed, randomized design with 2 intervention arms (intervention 1: telephone contacts; intervention 2: telephone contacts and short text messages; both took place over a period of 6 months and in addition to usual care), and a control group with usual care. Primary outcomes were 18-item Brief Symptom Inventory (BSI-18) scores for anxiety, depression and somatization. All participants were recruited from psychiatric day hospitals. The study was registered in the German Clinical Trials Register (DRKS00000662). **Results:** 113 participants were analyzed 6 months after starting the intervention. The average BSI-18 anxiety score after 6 months was –2.04 points lower in intervention group 2 than in the control group (p value: 0.042). The difference in BSI depres-

sion score between these two groups was marginally significant (p value: 0.1), with an average treatment effect of –1.73. In an exploratory sensitivity analysis restricted to the 75% of patients with the highest symptom scores at baseline, intervention group 1 yielded a significant effect for anxiety and depression compared to the control group (p = 0.036 and 0.046, respectively). **Conclusions:** Telemedicine provides a novel option in psychiatric ambulatory care with statistically significant effects on anxiety. A positive tendency was observed for depression, especially in cases with higher symptom load at baseline.

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Background

Mental disorders are common in the general population. The representative National Comorbidity Survey Replication in the USA showed a lifetime prevalence of 46.4% for any mental disorder, thereof 28.8% for anxiety disorders and 20.8% for mood disorders [1]. Similar numbers have been found for Germany, where the German Health Interview and Examination Survey gave a lifetime prevalence of 43% for any mental disorder, the most frequent ones being anxiety, mood and somatoform

disorders [2]. However, only a third of all affected people seek help for their condition [3, 4]. In Europe generally, only 26% of all patients with mental disorders have contact with health care services [5]. In Germany, 30% of patients without comorbidity make use of the health care system, and 76% of highly comorbid patients [2].

Direct costs related to depressive disorders have been estimated to amount to EUR 1.6 billion annually in Germany [6, 7], though indirect costs (e.g. absenteeism, disability, early retirement) are likely to be much higher.

In Germany, outpatient health care for patients with mental disorders consists of psychotherapeutic practices and psychiatric walk-in clinics. Apart from specialized clinics or departments in hospitals for inpatient treatment, there are day care hospitals for partial inpatient therapy. However, the availability of outpatient psychotherapists differs substantially between regions: the number of inhabitants per psychotherapist ranges from 2,577 in cities to 23,106 in rural regions [5]. Consequently, waiting lists, for example for the continuation of treatment after release from a psychiatric clinic or day hospital, can be very long.

To improve the treatment of underserved patients with mental disorders in rural regions, innovative and effective telemedical concepts using videoconferencing or telephone consultations need to be developed, tested and implemented, to supplement outpatient care.

Randomized controlled studies have shown that telemedicine concepts using internet and videoconference utilities can provide an alternative to face-to-face consultations, especially in rural regions. The acceptance among patients and psychotherapists is high, and clinical outcomes are comparable with usual care [8–11].

Telephone consultations are a low-threshold alternative to videoconferences. A number of studies in the USA including patients with depression have shown reductions of symptoms compared to usual care or face-to-face therapy [12–16].

In Germany, structured telephone interviews to assess depression symptoms conducted by practice assistants in general practices resulted in a significant decrease in the severity of depression symptoms [17].

Although Germany has large rural regions with a low coverage of outpatient psychotherapeutic health care services, concepts of innovative models of health care are still poorly developed.

To enable the continuation of the psychotherapeutic care after discharge from a psychiatric day hospital in the rural region of Western Pomerania in Northeast Germany, a low-threshold, proactive telemedical intervention was

designed. The intervention consisted of regular telephone consultations and short text messages (SMSs) sent to the patient's mobile phone. The primary goal of this study was the evaluation of the effects of the telemedicine intervention on the psychopathological outcomes anxiety, depressive symptoms and somatization. We hypothesized that, after 6 months, the intervention groups would have a better outcome compared to a control group receiving usual care.

A comprehensive description of the study protocol for this project is published in van den Berg et al. [18].

Methods

Participants

Participants for this study were recruited from 3 psychiatric day hospitals in Western Pomerania, who were preparing for their discharge after a 6- to 8-week treatment. All participating patients provided written informed consent after detailed consultation by their psychotherapist in the day hospital.

The inclusion criteria were a diagnosed depression, anxiety disorder, adjustment disorder or somatoform disorder. Exclusion criteria were:

- interval patients, defined as patients scheduled to return to the day hospital after 3–6 months to continue their therapy;
- a distinct emotional instability with recurrent suicide crises and/or self-injuring behavior.

Design

In a 3-armed, prospective, controlled, randomized design, 2 of the study arms included interventions with different intensities in addition to the usual care; the third arm was a control group receiving usual care.

Usual Care

Usual care means that the patients utilize health care services as needed and desired. This applies both to psychotherapy and to services in other health care areas, including medication. After discharge from the psychiatric day hospital, some patients continue their therapy in outpatient psychotherapeutic practices, while others have a longer waiting period, and some receive no subsequent therapy at all.

Intervention

Two different telemedical interventions were applied during a time period of 6 months, supplementary to the usual care:

- Intervention group 1: proactive, regular telephone contacts, conducted by specially trained nurses. The frequency of the telephone calls was once a week during the first month of the intervention, followed by monthly contacts for the remaining 5 months. If necessary, the frequency of the telephone contacts was increased. The telephone calls consisted of a standardized and a free part. The standardized part included standardized questionnaires to the severity of the anxiety, depressive symptoms or somatization (18-item Brief Symptom Inventory, BSI-18), the utilization of in- and outpatient care and medication,

as well as one question about the health situation of the patient, which was answered by the telemedicine nurse to monitor the patient over time. The free part of the calls included talks about important or unusual occurrences (e.g. with respect to family, relationship, job or health situation) and about the agreed therapy goals;

- Intervention group 2: in addition to the regular telephone contacts as in group 1, weekly SMSs, tailored to each individual patient, were sent. The SMS could refer to specific occurrences or therapy themes, but could also be more general and contain for instance good wishes for the upcoming weekend or public holiday.

The telemedicine contacts were conducted by trained nurses. Patients in both intervention groups were allowed to contact the nurses during office hours when desired.

Enrolment

The treating psychotherapist from the day clinic completed a short standardized enrolment form with personal data of the patient, diagnoses and medication. The patient's individual therapy goals and/or themes were elaborated between the psychotherapist and the patient (e.g. exposure to critical factors, including socializing with other people, dealing with family problems, creating a schedule for the day and the week). These goals were documented on the enrolment form, which was transferred to the telemedicine center. The individual patients were randomized to 1 of the 3 study arms.

During the telephone contacts and SMSs, the patient's individual therapeutic regimes were continued after day clinic treatment.

Measures

The clinical outcomes of the severity of the anxiety, depressive symptoms and somatization were assessed in structured computer-assisted telephone interviews [19] at baseline and after 6 months, using the symptom scales of the German version of the BSI-18. The BSI-18 is a standardized, reliable and valid self-report questionnaire with three 6-item symptom scales for depression, somatization and anxiety. The 18 items of the BSI-18 are answered on a 5-point Likert scale, ranging from 'not at all' (score: 0 points) to 'extremely' (score: 4 points), yielding a maximum score of 24 points for each symptom scale [20, 21].

The methods of the study, including a detailed description of the contents of the telephone calls (detailed description of the assessment of the utilization of health care services and medication, precise description of the questions about health situation, unusual occurrences and therapy goals) and text messages were described more comprehensively in a previous publication [18]. Here, detailed descriptions of the IT-supported documentation system, data storage data security and data protection are also available.

Statistical Analysis

Baseline characteristics were displayed as means (with standard deviations) for continuous variables and absolute numbers (with percentages) for categorical variables. Analysis of covariance was used to test average treatment effects on follow-up BSI-18 scores, while adjusting for baseline values of the corresponding BSI-18 score [22]. Intention-to-treat analyses were performed via chained equation multiple imputation [23]. For the imputation

models, baseline characteristics were examined for their association with loss to follow-up; variables related to loss to follow-up at $p < 0.15$ were included in the imputation model. All available baseline covariables were used for the chained imputation to produce 20 imputed data sets using Rubin's rules. To examine a possible floor effect in the data, an exploratory sensitivity analysis, excluding 25% of the patients with the lowest BSI-18 scores on the respective symptom scores, was conducted. Analyses were performed using Stata/MP4 13.1 (Stata Corp., College Station, Tex., USA).

The study was conducted in compliance with the ethical requirements of the institutional ethics committee of the board of physicians of Mecklenburg-Western Pomerania at the University of Greifswald (approval on June 30, 2009, reg. No. BB 50/09). The study is registered in the German Clinical Trials Register (DRKS00000662).

Results

Participants: Baseline Characteristics and Individual Goals of the Telemedicine Intervention

Although 141 patients were initially recruited from the day hospitals, 18 of them dropped out before the start of the project, resulting in baseline interviews being conducted with 123 patients (35 males, 88 females). The follow-up analysis was conducted with 113 participants. The main reason for dropping out was nonaccessibility by telephone, for example because the telephone number was not active anymore. The flow of the project is shown in figure 1.

The mean age of the patients at baseline was 44.0 years (standard deviation: 12.5 years); 91% ($n = 111$) of the participants had had at least 1 diagnosis in the spectrum of mood disorders (ICD-10 F30–F39), and 45.9% ($n = 56$) in the spectrum of neurotic, stress-related and somatoform disorders (ICD-10 F40–F48; table 1).

Upon discharge from the day hospital, all participants received individual goals, tasks to perform or specific instructions (table 2). Frequent goals and instructions included coping with specific health symptoms or problems ($n = 75$), work issues ($n = 48$), instructions to work on family and relationship problems ($n = 39$), organizing a day structure ($n = 36$) and establishing social contacts ($n = 34$). During the telephone contacts, the nurses asked the patients specifically whether they had been working on their goals. The patients in the intervention groups had an average of 12 telephone calls, the average duration of the calls being 57 min.

Of all patients with a follow-up, 62 (55%) had had at least 1 contact with a psychotherapist between baseline and follow-up.

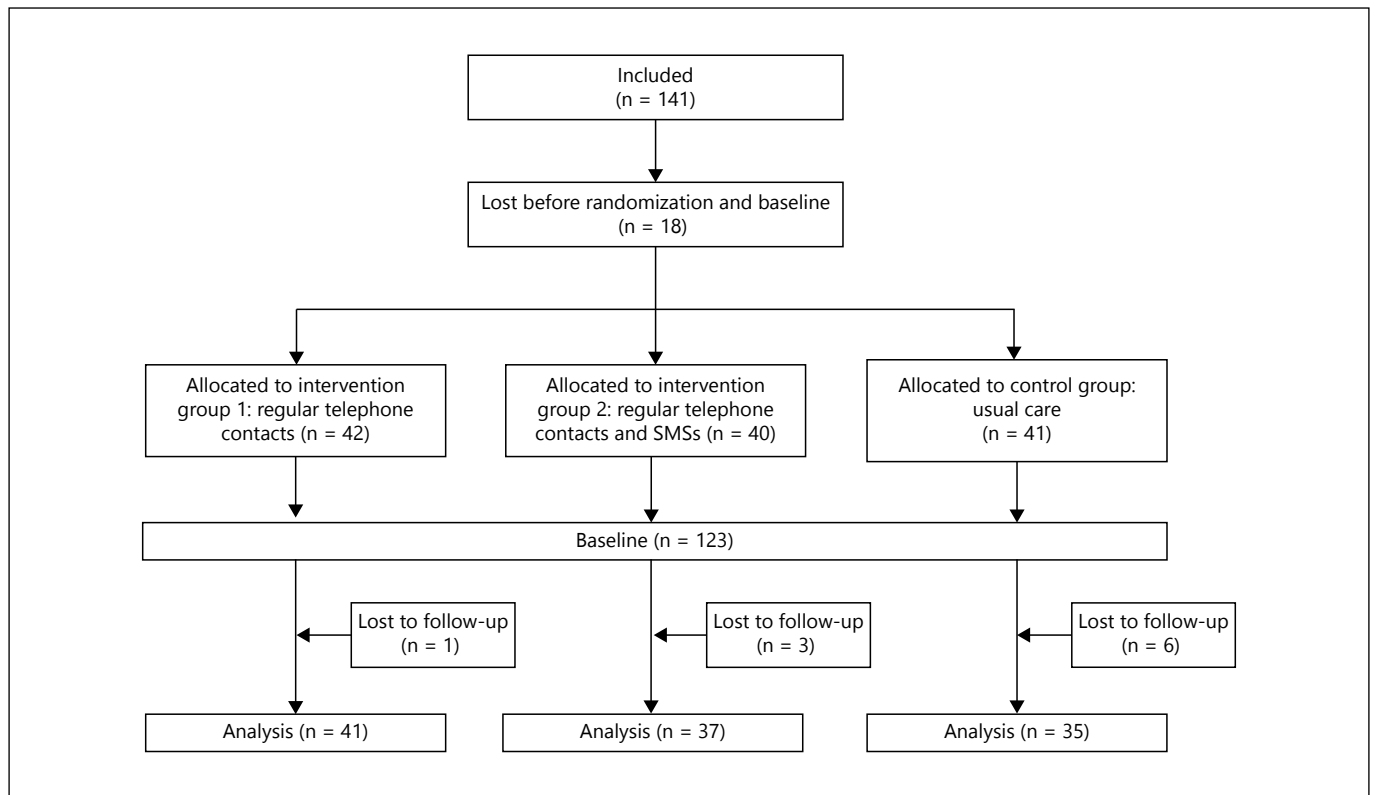


Fig. 1. Flow of participants through the trial.

Table 1. Baseline characteristics of the study participants

	Total	Intervention group 1	Intervention group 2	Control group
Participants, n	123	42	40	41
Mean age at baseline, years	44.0±12.5	46.4±14.0	42.9±12.5	42.5±10.5
Females	88 (71.5)	31 (73.8)	30 (75.0)	27 (65.9)
Psychiatric diagnoses ¹				
Organic mental disorder (ICD-10 F00–F09)	2 (1.6)	2 (4.8)	–	–
Mental and behavioral disorders due to use of psychoactive substances (ICD-10 F10–F19)	7 (5.7)	5 (11.9)	1 (2.5)	1 (2.5)
Mood disorder (ICD-10 F30–F39)	111 (91.0)	37 (88.1)	37 (92.5)	37 (92.5)
Neurotic, stress-related and somatoform disorders (ICD-10 F40–F48)	56 (45.9)	23 (54.8)	18 (45.0)	15 (37.5)
Behavioral syndromes associated with physiological disturbances and physical factors (ICD-10 F50–F59)	2 (1.6)	–	1 (2.5)	1 (2.5)
Disorders of personality and behavior in adult persons (ICD-10 F60–F69)	19 (15.6)	11 (26.2)	4 (10.0)	4 (10.0)
BSI-18 symptom scores at baseline				
Anxiety	6.91±4.63	7.60±5.09	7.43±3.71	5.71±4.79
Depression	7.15±5.33	8.71±5.22	7.10±5.18	5.61±5.26
Somatization	4.62±4.16	4.73±4.07	5.23±3.77	3.90±4.59

Results are expressed as means ± standard deviation or numbers with percentages in parentheses.

¹ Known for n = 122 participants.

Table 2. Patient individual goals, tasks and instructions given upon discharge from the day hospital

Goal/task/instruction	Number
Coping with disease, symptoms, health restrictions	75
Work-associated issues	48
Family, relationship issues	39
Organization or maintaining a daily and/or weekly structure	36
Establishing/cultivating social contacts	34
Carrying out leisure activities	31
Improving self-perception	29
Performing physical activity/sports	28
Continuing exposure therapy	23
Coping with routine activities/daily life	12
Conflict management	11
Improving communication skills	10
Changing the housing situation	3

Table 3. Posttreatment symptom scores, including means and standard deviations (in parentheses)

	Anxiety	Depression	Somatization
Intervention 1	6.71 (5.69)	6.27 (5.75)	4.76 (3.90)
Intervention 2	5.38 (4.02)	6.22 (5.59)	4.70 (3.99)
Control group	6.37 (5.80)	6.06 (5.70)	3.91 (4.31)

Effects of the Telemedicine Intervention

Table 3 shows the mean posttreatment symptom scores for each outcome and group at the follow-up after 6 months. Table 4 shows the average treatment effects for each intervention group compared to the control group. The average BSI-18 anxiety score at follow-up was -2.04 points lower in intervention group 2 than in the control group (p value: 0.042). Intervention group 1 and the control group did not differ with regard to the average BSI-18 anxiety score at follow-up. The difference between intervention 2 versus control on follow-up BSI-18 depression score was marginally significant (p value: 0.1), with an average treatment effect of -1.73 . Intervention group 2 and control condition did not differ with regard to follow-up BSI-18 depression scores. Likewise, follow-up BSI-18 somatization scores did not differ in the intervention groups and the control condition.

The baseline values of the symptom scores have a considerable influence on the outcome: higher symptom scores at baseline were positively associated with larger follow-up BSI-18 scores (table 3). An additional analysis

including the interaction between the baseline values of the respective baseline BSI-18 symptom scores and the treatment group showed no statistically significant results (p values for interaction >0.1 ; data not shown).

To examine a possible floor effect in the data, an exploratory sensitivity analysis was conducted, excluding 25% of the patients with the lowest BSI-18 scores on the respective symptom scores. This subgroup showed a significant effect of intervention 1 for anxiety and depression (p values of 0.036 and 0.046, respectively; table 5).

Discussion

A low-threshold telemedicine health care intervention was evaluated, consisting of telephone contacts and SMSs. The intervention was conducted by trained nurses for patients following treatment in a psychiatric day hospital. The main goal of this study was the evaluation of the therapeutic effects of telemedicine on the psychopathological outcomes anxiety, depressive symptoms and somatization.

Both the telephone contacts only and the more intensive intervention of telephone and SMSs had positive effects on the symptom scores for anxiety, the latter reaching statistical significance. A similar dose-response effect was not observed for depression, where a positive change was only observed for intervention group 1. No effect was observed in either intervention group for the somatization symptom score.

The intervention addressed patients shortly before discharge from a day hospital. This group is particularly at risk for a discontinuation of their psychotherapy, due to frequent long waiting periods for consecutive appointments in the ambulatory care system. Hence, it was tested whether telemedicine could compensate for this gap in an underserved region.

For anxiety and depression, baseline values were significant determinants for the effect sizes of their respective symptom scores. Higher symptom scores at baseline were associated with larger effect sizes of the telemedicine intervention. A sensitivity analysis including only 75% of the patients who had the highest symptom scores yielded a higher effect for telemedicine.

This study has some limitations. Patients were included by their psychotherapist on the basis of clinician diagnoses, irrespective of comorbidities or standardized cut-off scores for severity. Due to the broad inclusion criteria, our sample consisted of a patient group with high variances in the severity of the mental health disorders and

Table 4. Results of intention-to-treat analysis of covariance for the association of treatment groups on follow-up symptom scales of the BSI-18 (depression, anxiety and somatization)

Group	Follow-up BSI anxiety score		Follow-up BSI depression score		Follow-up BSI somatization score	
	β	p value	β	p value	β	p value
Control group (ref.)	0		0			
Intervention 1	-0.87 (-2.76 to 1.01)	0.364	-1.73 (-3.78 to 0.31)	0.097	0.49 (-1.05 to 2.04)	0.536
Intervention 2	-2.04 (-3.99 to -0.076)	0.042	-0.87 (-2.90 to 1.17)	0.403	0.17 (-1.45 to 1.78)	0.838
Baseline BSI score ¹	0.72 (0.53 to 0.89)	<0.001	0.69 (0.53 to 0.85)	<0.001	0.52 (0.36 to 0.68)	<0.001
Intercept	2.23 (0.61 to 3.85)	0.007	2.13 (0.47 to 3.78)	0.012	1.87 (0.58 to 3.17)	0.004

β = Coefficient from intention-to-treat linear regression based on multiple imputed data; figures in parentheses indicate 95% confidence intervals.

¹ Baseline BSI score of the corresponding dependent variable.

Table 5. Sensitivity analysis: results of intention-to-treat analysis of covariance for the association of treatment group on follow-up symptom scales of the BSI-18 (depression, anxiety and somatization), including 75% of the patients with the highest values for the respective BSI-18 symptom scores

Group	Follow-up BSI anxiety score upper 75%		Follow-up BSI depression score upper 75%		Follow-up BSI somatization score upper 75%	
	β	p value	β	p value	β	p value
Control group (ref.)	0		0			
Intervention 1	-1.29 (-4.00 to 1.39)	0.344	-2.75 (-5.45 to -0.052)	0.046	-1.700 (-4.79 to 1.39)	0.281
Intervention 2	-2.83 (-5.48 to -0.186)	0.036	-1.72 (-4.49 to 1.04)	0.223	-1.645 (-4.69 to 1.41)	0.290
Baseline BSI score ¹	0.65 (0.34 to 0.96)	<0.001	0.66 (0.424 to 0.908)	<0.001	0.380 (0.06 to 0.72)	0.022
Intercept	3.38 (0.039 to 6.73)	0.047	3.05 (-0.061 to 6.162)	0.055	5.750 (2.58 to 8.92)	<0.001

β = Coefficient from intention-to-treat linear regression based on multiple imputed data; figures in parentheses indicate 95% confidence intervals.

¹ Baseline BSI score of the corresponding dependent variable.

comorbidities. While on the one hand this heterogeneous group of patients may have reduced possible intervention effects, on the other hand, including this patient group provides for high external validity of the results and supports valid transferability to real health care.

The intervention included nurse-led talks regarding patient-individual goals and the assessment of symptoms. A more specific, evidence-based psychotherapy may have given more robust effects. For example, studies of Mohr et al. [13, 24] show strong effects for telephone-administered cognitive behavioral therapy.

Due to the pilot character of this study, the BSI-18 was chosen to measure the severity of the anxiety, depressive symptoms and somatization. Disease-specific measures

may have provided a more precise assessment of the severity of symptoms.

As the patients were recruited after treatment in a psychiatric day hospital, their clinical symptoms were well controlled. For the subgroup that had relatively low starting values of their symptom scores, limiting any further improvement, the therapeutic goal was to maintain their level at discharge from the day clinic, while the controls were expected to gradually decline. However, both intervention and control patients experienced only moderate to no declines of their symptom scores during the observation period.

Only one other published telemedicine study was found addressing anxiety. In a small study including pa-

tients after a treatment with mechanical ventilation (n = 8 participants at follow-up after 7 weeks), a telephone-based mindfulness training was conducted. In 75% of the participants, improvements in symptoms of psychological stress, including anxiety, were observed [25]. Other studies have confirmed positive effects of a supportive environment on anxiety [26, 27].

The effects of telemedicine interventions on depression have been examined in a number of other studies. The results of the current study align with these, although the settings and interventions strongly differ [12, 13, 16, 17]. In most studies, newly diagnosed patients or patients with unknown treatment status were included [12, 13, 17].

In a randomized controlled trial of newly diagnosed depressive patients, telephone therapy was compared with usual care for patients. The telephone psychotherapy intervention resulted in a significant reduction of depression severity [12].

In a US primary care setting, a telephone-based intervention for patients with major depression was not inferior to face-to-face therapy and showed less attrition [13]. A meta-analysis of 12 studies on the effects of telephone-administered psychotherapy on depression showed a significant reduction of depressive symptoms with telephone interventions compared to control conditions. Furthermore, the attrition rate was lower in telemedicine interventions than in face-to-face therapy [14].

Two studies in the USA examined telephone-based collaborative care for patients with depression in a primary care setting. The telemedicine-based interventions yielded a larger reduction of depression severity than the usual on-site care [15, 16].

In a pilot study in the USA, telephone monitoring was conducted with patients after at least 6 months of antidepressant treatment in specialty care (n = 104 patients). A follow-up after 6, 9 and 12 months, depression scores in the telemedicine group showed no significant differences to patients with usual care [28]. Despite similarities in intervention and setting, the results of this pilot study were less successful than in the current study. The main difference between the studies is the intensity of the intervention. In the study of Ludman et al. [28], patients were contacted once a month during the first 3 months of the intervention period. Subsequently, the frequency of the telephone contacts was more flexible. Our intervention started with weekly telephone contacts during the first month, followed by at least monthly contacts during the remaining 5 months [1, 28].

In Germany, a low-threshold intervention with standardized questions focusing on case management and

symptom monitoring for patients with depression was conducted in 74 primary care practices (n = 616 patients). A significant reduction of depression symptoms was observed [17]. This study is only marginally comparable with the current study because of differences between the health care sector and patient groups (primary care vs. specialty care) and between the interventions: in the interventions discussed here, individual therapeutic regimes were continued after day clinic treatment.

In summary, a proactive telemedicine intervention with telephone contacts and text messages had positive effects on anxiety and depression, especially for patients with a higher clinical severity of these mental health disorders. Hence, telephone-based interventions provide a means to continue therapy for these patients after day hospital treatment and to bridge the gap to consecutive ambulatory appointments, especially in regions with limited access to psychotherapeutic care. Further research in this area is necessary, including settings with patients with a worse treatment status, such as those on waiting lists for psychotherapeutic treatment, and more specified patient groups, allowing more disease-specific telemedicine treatment and monitoring. Furthermore, the effects of telemedicine interventions on the utilization of both psychotherapeutic and other medical services are of high relevance and need to be examined. A project to analyze these effects with regard to the interventions described here is in preparation.

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Disclosure Statement

The authors declare that they have no competing interests.

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