



Characteristics of participants in a randomized trial of an Internet intervention for depression (EVIDENT) in comparison to a national sample (DEGS1)



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ABSTRACT

Background: While the efficacy of Internet interventions for depression has been demonstrated in numerous studies, there is concern that the participants in these studies may systematically differ from depressed subjects in the general population. The goal of this study was to compare participants in a large trial of an Internet intervention for depression with a population-based sample that reported depressive symptomatology in the same range of severity.

Methodology: The analysis is based on a sample of participants of a randomized controlled trial testing the effectiveness of an Internet intervention for depression in mild to moderate depression (EVIDENT, $N = 1013$) and a subsample of participants in a representative population-based sample (DEGS1, $n = 1978$). The DEGS1 subsample was chosen based on the score in the Patient Health Questionnaire-9 (PHQ-9, score 5–14) as this was the main inclusion criterion for the EVIDENT study. Both samples were compared with respect to a range of demographic and clinical variables.

Results: Compared with the DEGS1 subsample, participants in the EVIDENT sample were significantly more often female (68.6% vs. 56.3%), slightly older (mean age 42.9 vs. 40.4 years), had more often completed highest secondary education (51.3% vs. 22.4%), were clinically more severely affected (moderate depressive symptoms in 62.6% vs. 18.3%) and reported a lower quality of life.

Conclusion: These findings indicate that participants in this Internet trial were not just internet savvy young males without significant impairment. Future studies should aim to recruit participants with lower educational status to increase the reach of Internet interventions.

1. Introduction

Depression is a serious public health problem (Kessler et al., 2005) and, apart from anxiety disorders, depressive disorders are the most prevalent mental disorders (World Health Organisation (WHO), 2005). Despite the considerable disability associated with depressive symptoms (Murray et al., 2012), a high proportion of affected individuals remain untreated, even in well-developed health care systems, such as the one established in Germany (Mack et al., 2015).

The reasons underlying this treatment gap include the limited access to mental health professionals who are qualified in diagnosis and treatment of depression, but also fear of social stigma, which results in reduced readiness to seek professional help for those concerned (Schomerus and Angermeyer, 2008). Many other barriers that keep depressed persons from accessing psychological therapies have been identified, including time constraints, lack of motivation, and the perception that therapy might not fit personal needs or might be ineffective (Mohr et al., 2010).

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Internet-based depression interventions can be an appropriate component of treatment for persons presenting with mild to moderate symptoms (National Institute for Health and care Institute (NICE), 2009). Also it has been shown that Inter-based interventions can be effective in the treatment of more severe depressive symptoms (Meyer et al., 2015). These treatments are more easily accessible than face-to-face therapy, they are less costly, and they can be used flexibly even if time is limited (Hedman et al., 2012). The efficacy of a range of Internet interventions for depression has been demonstrated in a number of meta-analyses (Bower et al., 2013; Cuijpers et al., 2011; Karyotaki et al., 2017; Richards and Richardson, 2012), although the methodological quality of many trials has been criticized (e.g., reliance on self-report data, short follow-up periods, few active control conditions). One often cited limitation is that Internet intervention trials recruit convenience samples of Internet-savvy young male adults without clinical symptom severity or psychosocial impairment that are not representative of depressed subjects in the general population (Arnberg et al., 2014; Kiluk et al., 2011).

This concern warrants further investigation because to our knowledge only two studies have actually compared participants of such trials with population-based samples. Consequently, little is known about the characteristics of individuals seeking the help of Internet interventions compared with subjects from the general population who are suffering from mental disorders. One study that included participants with either an anxiety or depressive disorder suggests that Internet-based treatments may reach people who are as severely affected as patients in an outpatient clinic, but who are surprisingly older than outpatients (Titov et al., 2010). Participants in both treatment groups in that study were more highly educated than respondents in a national sample of similarly affected patients.

Another study compared participants with obsessive compulsive symptoms in an Internet survey with people with OCD identified in a national epidemiological survey and with a sample of patients with OCD from a specialist outpatient anxiety clinic (Wootton et al., 2011). The Internet sample was similar demographically but reported more severe symptoms than the comparison groups, although they had similar severity of symptoms of OCD compared with other clinical samples reported in the literature. However, these findings require replication.

In the present study, we examined whether participants in a randomized trial (the EVIDENT study) differed from a representative depressed population sample (DEGS1) with a similar range of depressive symptom severity with respect to demographic or clinical characteristics.

2. Method

2.1. Participants

2.1.1. The EVIDENT trial

The EVIDENT trial (Effectiveness of Internet-based DEpression Treatment) is a multicenter randomized controlled trial that demonstrated effectiveness of an Internet-based self-help program for treating mild to moderate depressive symptoms (Klein et al., 2016).

The EVIDENT trial targeted adult participants (age between 18 and 65 years) with mild to moderate depressive symptoms (PHQ-9 score between 5 and 14). The restriction of the severity range was due to the fact that guidelines recommend the use of low intensity interventions including Internet interventions for this population (National Institute for Health and Clinical Excellence, 2015). Participants were recruited between August 2012 and December 2013 from different sources, including inpatient and outpatient medical and psychological clinics, online-forums for depression, health-insurance companies and the media (e.g., newspaper). After registration at the study website and providing informed consent, participants were asked to complete online questionnaires assessing demographic data, depressive

symptomatology as measured by the Patient Health Questionnaire-9 (PHQ-9) as well as health-related quality of life measured by the Short-Form Health Survey-12 (SF-12) (Ware et al., 1996). All instruments were administered via an online survey platform, as there is evidence that this produces valid results (Fann et al., 2009; Van Gelder et al., 2010). Presence of acute suicidality and a history of bipolar or psychotic disorders led to exclusion from the study. A total of 1013 participants were included and randomized.

2.1.2. The DEGS1 study

Data from the German Health Interview and Examination Survey for Adults (DEGS1) were used for comparison. The DEGS1 study is part of the national health monitoring program in Germany. It was conducted in 2008–2011 to obtain comprehensive information about the health of the non-institutionalized population aged 18–79 years in Germany. The survey initially comprised a sample of 7988 men and women. Data were collected by self-administered written questionnaires, standardized physician-administered computer-assisted personal interview (CAPI) and a range of physical, laboratory and other measurements. The design, objectives and methods of DEGS1 have been described in detail elsewhere (Busch et al., 2013; Gößwald et al., 2013; Kamtsiuris et al., 2013; Scheidt-Nave et al., 2012). To ensure comparability with the EVIDENT sample, we selected a subsample from DEGS1 only including participants that were aged between 18 and 65 years with a score between 5 and 14 on the PHQ-9 scale. This subsample comprised $n = 1978$ individuals.

2.2. Demographic characteristics and symptom severity

Sociodemographic characteristics assessed in the study included age, sex, marital status, education, and employment status. Data were assessed either online as a self-report in the randomized trial (EVIDENT) or via interview and questionnaires in the DEGS1 survey.

2.2.1. Instruments

The German version of the nine-item depression module of the Brief Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2010; Löwe et al., 2004) is a widely used self-report inventory of depressive symptom severity. Participants with a score between 5 and 9 on the PHQ-9 scale can be classified as mildly depressed and a score between 10 and 14 on the PHQ-9 scale indicates moderate depression (Kroenke et al., 2010; Maske et al., 2015). Apart from the total sum score to estimate symptom severity dimensionally, a diagnostic algorithm, developed by the instrument's authors, was used to estimate the proportion of respondents with a likely diagnosis of current major depressive episode. To meet criteria in this algorithm, patients have to indicate on at least five of the nine items that symptoms occurred “more than half the days” (item 9 – suicidal ideation – is also counted if patients report “on several days”) (Kroenke et al., 2010; Löwe et al., 2004). The psychometric properties of the PHQ-9 are excellent, with high internal consistency, test-retest reliability, criterion validity, comparatively favourable sensitivity and specificity, and good sensitivity to change (Kroenke et al., 2010).

The Short Form Health Survey - 12 (SF-12) is a commonly used measure of health-related quality of life (Ware et al., 1996). The twelve items assess the presence and severity of various aspects of functioning, as well as role limitations due to physical and emotional health problems over the course of the last 4 weeks. It yields two summary scores: physical well-being and mental well-being. Psychometric properties, including test-retest reliability, internal consistency and convergent validity, are good to excellent, and comparable to its longer version, the SF-36 (Jenkinson et al., 1997; Salyers et al., 2000).

2.3. Statistical analysis

Statistical analyses were conducted using SPSS 20.0 (IBM SPSS

Table 1
Demographic and clinical variables.

Variable	Sub-variable	EVIDENT		DEGS1	
		(n = 1013)		(n = 1978)	
		N	Mean or percentage (95%CI)	N	Mean or percentage (95%CI)
Gender	Male	318	31.8 (28.6–34.2)	791	43.8 (41.3–46.3)
	Female	695	68.6 (65.8–71.4)	1187	56.3 (53.7–58.7)
Age	Mean Age	1013	42.9 (42.2–43.5)	1978	40.4 (39.8–41.1)
	Marital Status				
	Married & cohabitating	425	42.0 (38.9–45.2)	1066	51.9 (49.0–54.8)
	Married & living apart	28	2.8 (1.9–3.8)	17	0.7 (0.4–1.3)
	In relationship	189	18.7 (16.2–21.0)	456	24.7 (22.4–27.3)
	Divorced	115	11.4 (9.5–13.3)	66	2.8 (2.0–3.9)
	Single	247	24.4 (21.8–27.0)	297	17.7 (15.6–20.0)
	Widowed	9	0.9 (0.4–1.5)	45	2.2 (1.6–3.1)
Education	Graduating	2	0.2 (0–0.5)	25	1.8 (1.1–2.8)
	No graduation	1	0.1 (0–0.4)	25	1.5 (1–2.2)
	Lower secondary	53	5.2 (3.8–6.8)	434	25.2 (22.6–28)
	Middle secondary	243	24.0 (21.5–26.6)	842	41 (38.1–43.9)
	Higher secondary	172	17.0 (14.7–19.2)	144	6.3 (5.1–7.9)
	Highest secondary	520	51.3 (48.2–54.5)	475	22.4 (19.7–25.4)
	Other	22	2.2 (1.3–3.1)	23	1.8 (1.1–3)
Employment Status	Full time	434	42.8 (39.6–45.8)	892	45.8 (43–48.7)
	Regular part-time	231	22.8 (20.3–25.8)	323	16.2 (14.3–18.2)
	One-euro job	2	0.2 (0.0–0.5)	14	0.8 (0.4–1.4)
	Marginally employed	45	4.4 (3.3–5.8)	201	11 (9.3–13)
	On parental leave/holiday	21	2.1 (1.3–3.1)	35	1.5 (1–2.1)
	Others	91	9.0 (7.2–10.9)	45	2.6 (1.9–3.6)
	Unemployed	245	24.2 (21.5–26.9)	456	22.2 (19.9–24.7)
PHQ-9 Score	5–9	379	37.4 (34.3–40.2)	1623	81.7 (79.4–83.8)
	10–14	634	62.6 (59.8–65.7)	355	18.3 (16.2–20.6)
Depressive disorder (2)	Yes	146	14.4 (14.0–15.2)	62	3 (2.2–4.2)
	No	867	85.6 (85.1–91.5)	1916	97 (95.8–97.8)
SF-12 Score	Mean Physical Score	1013	47.6 (47.0–48.2)	1949	50.9 (50.4–51.5)
	Mean Mental Score	1013	31.3 (30.9–31.8)	1949	42.7 (42.1–43.2)

(1) Secondary education according to the German classification: “Hauptschule” (“lower”, 9 years, until age 15/16), “Realschule” (“middle”, 10 years, until age 16/17), “Fachhochschulreife” (12 years, until age 17/18), “Abitur” (12 or 13 years, until age 17–19).

(2) According to the PHQ diagnostic algorithm.

Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.) and Strata. Differences between sample means were calculated using 95% bootstrap confidence intervals. Bootstrap resampling was set at 1000 cases. Statistically significant differences between the means of a variable from both groups can conservatively be assumed when their estimated 95% confidence intervals do not overlap (Schenker and Gentleman, 2001).

3. Results

3.1. Demographic characteristics

Detailed sociodemographic data for each group are provided in Table 1. Briefly, participants differed significantly in a number of sociodemographic characteristics: sex, age, marital and employment status and educational qualification. Specifically, in the EVIDENT sample, there was a stronger predominance of women (6% versus 56%), more participants were single or divorced, and individuals were on average 2.5 years older than those from the DEGS1 sample. Further, participants in this trial reported significantly higher educational qualifications and a significantly higher proportion of part-time employment than the DEGS1 sample.

3.2. Symptom severity

Detailed symptom severity data for each group are provided in Table 1. Briefly, participants showed significant differences in clinical characteristics between groups. Even though the range of depressive symptoms was matched (i.e., PHQ-9 range from 5 to 14), individuals in the EVIDENT sample reported significantly higher depressive symptom

severity than the DEGS1 sample. Consistent with the higher level of depressive symptom severity in the EVIDENT sample, individuals reported significantly lower health-related quality of life shown on both scales of the SF-12 compared to the DEGS1 sample.

4. Discussion

The present study found a number of differences in demographic and clinical characteristics between participants in a randomized trial of an Internet intervention for depression (EVIDENT) and depressed participants in a population-based survey (DEGS1) with the same range of depressive symptom severity. Participants in the EVIDENT trial were older, more often female, more often single or divorced, more highly educated, and less often employed full-time than individuals from the DEGS1 sample. They also reported more severe depressive symptoms and a lower health-related quality of life.

The higher symptom severity in the EVIDENT sample can be explained by the differing recruitment strategies: the EVIDENT trial recruited a sample of help-seeking individuals whose higher depression score might have been the reason for participation in a randomized controlled trial for an Internet intervention. In contrast, participation in the population-based DEGS1 study was unrelated to help-seeking motivation.

Most but not all of the demographic differences can be explained by the higher symptom severity observed in the EVIDENT sample. Firstly, the higher proportion of females is likely due to the higher prevalence of depression in females. Numerous studies found a higher risk for depressive disorders in women in the German population, with prevalence rates of moderate depression (PHQ-9 score ≥ 10) twice as high among women compared to men (Maske et al., 2015). A further

explanation for the higher percentage of women in the EVIDENT study could be that participants here were given the opportunity of treatment for their depressive symptoms and women differ in their help-seeking behavior from men. Particularly, a cross-sectional study showed that women with common mental health problems were more likely to seek help than men (Oliver et al., 1988).

Also, a frequently reported finding is that the rate of divorce is higher among depressed than among healthy individuals (Wade, 2000). The Epidemiologic Catchment Area Study found that divorced or separated persons showed a two- to four-fold increased risk of major depression compared to married persons (Weissman et al., 1996). This could explain the higher proportion of single or divorced individuals in the EVIDENT sample compared to the DEGS1 sample.

Two findings are unlikely to be due to more severe depressive symptoms in the EVIDENT sample: the slightly higher age and the substantially higher educational status. Cross-sectional studies found that a lower educational status is associated with a higher prevalence of depression (Lorant et al., 2003). However, participants in the EVIDENT trial reported higher educational status as well as more elevated depressive symptoms than participants in the DEGS1 sample. It could be argued that the demand for Internet interventions is higher for people with a higher educational level which was shown for user of an internet-delivered lifestyle intervention (Brouwer et al., 2010). Also, this study has found that individuals were more likely to repeatedly use the intervention if they were female. It is noteworthy that the EVIDENT sample was slightly older than the DEGS1 sample.

Our findings are in line with previous studies comparing samples from the Internet with national samples. In one study participants from an outpatient clinic, a national sample and an Internet clinic were compared to each other (Titov et al., 2010). Here, participants from the national sample also showed lower levels of symptom severity in comparison to those from the Internet trial whose symptoms were as severe as those found in the clinical outpatient sample. Also, participants in the Internet clinic were older than those attending the outpatient clinic. Most importantly, participants in both treatment groups in that study were more highly educated than respondents in the national sample. It can be noted that subjects with lower and middle secondary education might be underrepresented in clinical trials for depression (Schramm et al., 2017).

Another study focusing on obsessive compulsive symptoms compared participants in an Internet survey with people with OCD identified in a national epidemiological survey and with a sample of patients with OCD from a specialist outpatient anxiety clinic (Wootton et al., 2011). Although the Internet trial sample was similar demographically compared to the national and clinical samples, participants reported more severe symptoms than the comparison groups.

A number of strengths and limitations of the present study ought to be mentioned. Firstly, strengths include the large sample sizes in both groups, particularly when compared to other studies in this field. Secondly, participants in the Internet trial were recruited from a broad range of sources, which increases the generalizability of our findings. Thirdly, outcomes of the study were measured by established and well validated assessment instruments.

Limitations include the different assessment methods used in the samples that we compared. In the national sample, participants were mainly examined in a face-to-face interview, whereas in the Internet trial, online self-report scales were used. However, research suggests that method of administration (i.e. paper vs. online assessment of symptoms) may not change results (Bjorner et al., 2014). A further limitation is that the Internet trial included primarily individuals recruited from sources other than clinical settings, such as Internet forums. This is unlikely to have affected the results of this study though as the recruitment source has been found not to be associated with most of the demographic and clinical parameters that we have studied here (Klein et al., 2017). Also, participants in the EVIDENT study may differ from people using Internet Interventions in general. It could be argued

that affected individuals with a higher educational level are more likely to participate in a randomized control trial for an Internet intervention than individuals who are less educated. An Australian community survey investigated coping behavior with depressed participants. Here, better educated people had greater use of some self-help interventions (Jorm et al., 2004).

Finally the restriction of symptom severity to mild to moderate depression limits the generalizability of the findings to more severely affected individuals with a PHQ-9 score higher than 14.

We conclude that the participants in our Internet intervention study were not just Internet savvy young males without significant impairment. Rather they were mostly women who suffered from considerable depressive symptoms resulting in a diminished quality of life. These were even slightly older than the subjects from the population sample. We must also conclude though that our study has not sufficiently reached one particular demographic group: depressed subjects with a lower or middle secondary education. Given that this demographic is underrepresented in RCT samples, efforts should be made to make psychological interventions more attractive for less highly educated subjects. One option to include a broader field of participants could be the use of therapeutic games or comics (Merry et al., 2012). These efforts might contribute to fulfilling the promise of Internet interventions: reaching a broader group of patients than the current forms of treatment.

Conflict of interest

JPK received payments for presentations, workshops and books on psychotherapy for chronic depression and on psychiatric emergencies. BM is employed as research director at GAIA AG, the company that developed and owns the internet intervention investigated in this trial. All the other authors report no relationships with commercial interests.

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