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# Effects of patient-driven iCBT for anxiety in routine primary care and the relation between increased experience of empowerment and outcome: A randomized controlled trial

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#### ABSTRACT

*Background:* The World Health Organization has declared that primary care should be organized to empower individuals, families, and communities to optimize health. Internet cognitive behavioral therapy (iCBT) tailored by psychologists' initial assessments to meet patients' specific needs have shown promising effects. However, few studies have evaluated patient involvement in decisions during iCBT.

*Aim:* This study aimed to explore the effect of patient-driven iCBT compared to standard iCBT on perceived control over treatment, adherence, and level of anxiety symptoms. A secondary aim was to assess the relationship between changes in empowerment and changes in anxiety symptoms.

*Method:* Participants were patients recruited form primary care and assessed as meeting the criterion for an anxiety disorder. Participants were randomized to patient-driven iCBT (n=27) or standard iCBT (n=28). Patient-driven iCBT was adapted to participants' preferences regarding for example focus of treatment program and order of modules. Participants randomized to the control condition received the standard iCBT program for anxiety disorders at the participating unit. The outcome measures were patients' perceived control over treatment, adherence to treatment, symptoms of anxiety, depression and general disability as well as the experience of empowerment.

Results: Participants in patient-driven iCBT had statistically higher perceived control over treatment (t(43) = 2.13, p = .04). Symptoms were significantly reduced in both arms with regards to anxiety, depression, and general disability. A significant time per condition interaction effect for anxiety symptoms was observed (df = 45.0; F = 3.055; P = .038), where the patient-driven condition had a significantly larger reduction in anxiety. For both groups a significant correlation of r = -0.47 was found between changes in empowerment and changes in anxiety.

Conclusion: Results indicate that iCBT that is patient-driven, may have a greater effect on anxiety, than standard iCBT. The effect on perceived control over treatment might also be larger in patient-driven treatments than in standard iCBT. Internet-based therapies inherently promote as active agents of their own care and might be well suited for promoting perceived control and empowerment. Findings need to be replicated given the small sample size and the explorative nature of the study.

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#### 1. Background

The World Health Organization (WHO) has developed a definition of primary care based on three important components: (1) meeting people's lifelong health needs and strategically prioritizing key health services, (2) using evidence-based policies to address determinants of health such as social, economic, and environmental factors and individuals' characteristics and behaviors, and (3) empowering individuals, families, and communities to optimize their health (WHO, 2018). About 54% of primary care patients present with common mental disorders; the most prevalent being affective disorders (35.8%) followed by anxiety disorders (25.6%). The comorbidity rate is high, and 30% of affected patients have more than one current mental disorder (Roca et al., 2009).

In primary care, there is a general gap between the needs for mental health treatment and access to care (Kohn et al., 2004). Internet-delivered Cognitive Behavioral Therapy (iCBT) may be beneficial by increasing the availability of care through requiring less therapist time, incurring lower health care costs, bridging geographical distances by providing flexibility in the time and location of treatment delivery, and reducing stigma associated with seeking care. The positive effect of iCBT in adults with anxiety disorders is well-known (Andersson, 2018) and comparable to face-to-face therapy in primary care settings (Eriksson et al., 2017; Flygare et al., 2019). Despite the positive results of iCBT, however, dropout from treatment is common (Eriksson et al., 2017; Christensen et al., 2009; van Ballegooijen et al., 2014). A systematic review and meta-analysis showed that dropouts from treatment averaged 15.7% for therapy-supported iCBT, although this did not differ significantly from dropouts in face-to-face treatment (Carlbring et al., 2018).

In recent years, the health care system has shifted toward personcentered care and focused on the importance of patients as active agents and increasing their involvement in their own health care. The World Health Organization (WHO) uses the Ottawa Charter for Health Promotion (World Health Organization, 1986) as their policy document to guide their international public health work (1997), defined as: "[...] the process of enabling people to increase control over, and to improve, their health" (1997, s. 4). This process should be characterized by empowering individuals with a greater chance to influence and improve their own health. Person-centered care is also consistent with evidencebased medicine (Britten et al., 2020), the practice of which rests on three pillars: (1) the best available evidence from research and science, (2) the professional's own expertise in considering this evidence to inform treatment choices, and (3) the professional's consideration of the patient's individual situation, preferences, values, and wishes (American Psychological Association, Presidential TaskForce on Evidence-Based Practice, 2006). Empowering patients by deferring to their own preferences might be a key mechanism in positive change. Nevertheless, more research is needed to understand the mechanisms of change in treatment outcomes (Hayes and Hofmann, 2018).

The concept of empowerment has its foundation in a political context and was originally used by various citizen movements to signify experiences of social marginalization and the struggle for equal rights, social and cultural justice. Empowerment is now seen as a multidimensional concept including psychological, social, and political components (Rogers et al., 2010) and comprising dimensions such as self-esteem, power, community activism, righteous anger, and optimism-control over the future (Rogers et al., 1997). Empowerment revolve around believing in oneself, which is assumed to increase self-determination and influence (Cattaneo and Chapman, 2010). Rogers et al. (1997) stated that empowerment consists of a sense of self-worth, self-efficacy, and power. The empowered person recognizes the use of anger as a motivating force to instigate social change and is optimistic about the ability to exert control over his or her life. When patients are given the opportunity to influence treatment and adapt it to their needs, their empowerment is expected to increase.

Recent studies have shown that accommodating patient treatment

can directly influence treatment outcomes (Adamson et al., 2008; Mergl et al., 2011; Williams et al., 2016). Acceding to client preferences has been associated with improvements regarding both treatment satisfaction, treatment completion, and clinical outcomes (Lindhiem et al., 2014; Swift et al., 2018). A meta-analysis concluded that accommodating the patients' preferences regarding treatment for mental health conditions was associated with decreased dropout rates, a stronger therapeutic alliance, but not with clinical outcomes (Windle et al., 2020). In a recent double-randomized controlled preference trial, participants were randomized to either choosing between psychodynamic or cognitive behavioral therapy aimed at panic disorder or being randomly allocated to one of the two treatments or to a wait-list control group. Results showed no between-group differences in primary outcomes for symptom reduction, absence from work, nor employment status at the end of treatment nor at the 2-year follow-up assessment. In addition, participants randomized to a treatment were no less likely to drop out than the participants who were able to choose the treatment they preferred (Svensson et al., 2021).

iCBT tailored by psychologists' initial assessments to meet patients' specific needs have shown promising effects (Andersson et al., 2011; Nordgren et al., 2012; Kraepelien et al., 2018; Kraepelien et al., 2019; Păsărelu et al., 2017; Weineland-Strandskov et al., 2017; Zagorscak et al., 2020). However, to date, treatment effects of routine primary care iCBT tailored to the preferences of patients suffering from mental health issues are still unknown. To explore the effect of patient-driven treatment compared to treatment as usual, we designed a randomized controlled trial in routine primary care, where patients in the experimental condition could express preferences in several domains of therapeutic digital care. The importance of a range of choices has been expressed in the previous literature. In a national survey conducted in England and Wales, Williams et al. (2016) found that most people had at least one preference regarding their treatment, such as the venue where treatment was delivered, the time of day of appointments, gender of the therapist, language in which the treatment was delivered and type of therapy. Furthermore, the authors found that patients reporting that their preferences had not been met were less likely to agree that the therapy had helped them, particularly when patient preferences for a specific type of therapy were not met (Williams et al., 2016).

In this study, the participants that were randomized to the experimental condition could choose which of the treatment programs they wanted to complete: anxiety, worry, stress, sleep disorders, or depression. Furthermore, the patients in the experimental condition could choose how many modules in the treatment program they wanted to receive and in what order and whether they would receive new modules every week or every other week. Regarding the contact with their therapist the participants were also asked how often they wanted telephone contact with their therapist and whether or not they wanted to receive regular written feedback from their therapist. Hence, the experimental patient-driven condition was patient-controlled in choices, whereas the control group received standard iCBT being healthcare staff-controlled in choices. We did not want to narrow the available choices in the experimental condition, but instead include the broad spectrum of available choices in order to maximize the amount of experimental manipulation of the patient-driven elements.

iCBT is largely based on self-help and the patient's own ability to implement changes while there is also a risk of the highly standardized treatment material being perceived as impersonal and not adapted to the needs of the individual. The process of empowerment might have special significance in iCBT, in such a way that when patients are given the opportunity to influence treatment and adapt it to their needs, their empowerment is expected to increase and this might be significant in iCBT. Empowerment might be a key concept in the theoretical model, but we are not aware of any study investigating the association between empowerment and symptom reduction in internet-delivered psychological treatments.

#### 1.1. Objectives

This randomized controlled trial (RCT) is aimed to explore the effect of making iCBT more patient-driven on patients' perceptions of their control over the treatment, their compliance with treatment, and their symptoms of anxiety. The study is also aimed to assess the relationship between changes in empowerment and changes in anxiety symptoms.

# 2. Method

# 2.1. Design

This study was a randomized controlled study (RCT) with two arms. 56 participants were recruited and randomized to one out of two treatment conditions: (1) patient-driven iCBT and (2) standard iCBT. The study was approved by the Swedish Ethical Review Authority (Dnr: 2019-03786).

# 2.2. Participants

The participants were recruited from patients seeking care in primary care and assessed as meeting the criterion for at least one anxiety disorder. The inclusion criteria required being 18 years old or older, having access to a computer, mobile phone, or tablet with internet connection, being able to speak and understand Swedish and meeting the diagnostic criteria for an anxiety disorder (social anxiety, generalized anxiety disorder [GAD], panic disorder, obsessive-compulsive disorder, or unspecified anxiety disorder). Exclusion criteria were having started medication for mental illness or made major changes in medication during the past 4 weeks, having serious suicidal thoughts or suicidal plans, having complex comorbidity, needing other care for mental illness in addition to iCBT, or receiving other psychological treatment during the treatment period.

Participants were recruited between November 2019 and March 2021. 69% of the participants were 35 years old or younger, 50.9% were employed full-time, 65.5% had received previous psychological treatment, and 45.5% used psychopharmacological treatment during the study period. Twelve participants (22%) met the criteria for GAD as their main diagnosis, 9 (16%) for panic disorder, 4 (7%) for health anxiety (hypochondria), 2 (4%) for social phobia, 1 (2%) for obsessive-compulsive disorder, and 27 (49%) were classified as having an unspecified anxiety disorder. Table 1 shows the demographic variables of the participants.

# 2.3. Procedure

Participants were recruited from clinical patients in primary care who had been referred to a central unit for iCBT in the Västra Götaland region in Sweden. Before initiating treatment, the participants were interviewed by a psychologist using a structured diagnostic interview called Mini International Neuropsychiatric Interview (MINI version 7.0.1) (Sheehan et al., 1998). The diagnostic interview was conducted via video call upon referral from the primary health care centers. After the assessment interview, all patients who were offered iCBT and met the inclusion criteria were asked to participate in the study. Twenty-two patients, 27.66%, of the patients assessed for eligibility, declined to participate in the study. One of the researchers called all participants who had agreed to participate and informed about the study and performed the randomization. Participants had both verbal and written information about the study and were able to ask questions. The groups were predetermined using the randomizer.org tool and blinded to the researcher assigning the participants to groups.

Participants randomized to the experimental condition, patient-driven iCBT, were asked during the telephone call to make choices regarding the structure of their treatment. Participants received a secure link by email where they were asked to fill in measurement forms for the

**Table 1** Demographic variables of participants.

Variable		Treatment condition (patient-driven) N = 27	$\begin{array}{c} \text{Control} \\ \text{condition} \\ \text{(standard} \\ \text{treatment)} \\ N=28 \end{array}$	Total
Age Frequencies (%)	18–25 years 26–35 years 36–45 years 46–55 years 56–65 years 66–75 years Older than 75 years	5 (18.5) 12 (44.4) 8 (29.6) 1 (3.7) 0 (0) 1 (3.7) 0 (0)	8 (28.6) 13 (46.4) 3 (10.7) 3 (10.7) 1 (3.6) 0 (0) 0 (0)	13 (23.6) 25 (45.5) 11 (20) 4 (7.3) 1 (1.8) 1 (1.8) 0 (0)
Gender Frequencies (%)	Man Woman Other	10 (37) 17 (63) 0 (0)	6 (21.4) 22 (78.6) 0 (0)	16 (29.1) 39 (70.9) 0 (0)
Occupation Frequencies (%)	Employed. full- time Employed. part- time Unemployed Student Sick-leave Parental leave	15 (55.6) 6 (22.2) 0 (0) 5 (18.5) 0 (0) 1 (3.7)	13 (46.4) 7 (25) 0 (0) 5 (17.9) 0 (0) 3 (10.7)	28 (50.9) 13 (23.6) 0 (0) 10 (18.2) 0 (0) 4
Previous psychological treatment Frequency (%)	Yes No	18 (66.7) 9 (33.3)	18 (64.3) 10 (35.7)	(7.3) 36 (65.5) 19 (34.5)
Other psychological treatment during time for iCBT	No PDT CBT Other psychological treatment/ Counseling	18 (64.3) 0 0 2 (7.4)	18 (64.3) 0 1 (3.6) 3 (10.7)	36 (65.5) 0 (0) 1 (9.1) 5 (9.1)
Current antidepressant medication Frequency (%)	Yes No	8 (37) 17 (63)	19 (64.3) 11 (35.7)	27 (49.0) 28 (51.0)
Diagnosis Frequency (%)	Generalized anxiety disorder (GAD) Panic disorder Social phobia Health anxiety Obsessive- complulsive disorder (OCD) Unspecified anxiety disorder	6 (22.2) 3 (11.1) 0 (0) 4 (14.8) 1 (3.7) 13 (48.1)	6 (21.4) 6 (21.4) 2 (7.1) 0 (0) 0 (0) 14 (50.0)	12 (22) 9 (16) 2 (4) 4 (7) 1 (2%) 27 (49)

pre-assessment, following which they were given access to the treatment program. Participants were then asked to fill in follow-up measurement forms sent to their email through the digital link at the middle of the treatment (by module 4), at the end of the treatment (by module 8), and at the 3-month follow-up assessment. For safety reasons, participants in the treatment program also answered a weekly question on suicidal ideations.

A power analysis for the sample size showed that a minimum of 90 participants should be included for a two-tailed hypothesis test to find an effect size of d=0.6 for easy comparison of mean values between the two treatment groups for perceived control over the treatment. A total of 56 participants were included in the study, 28 randomized to the intervention condition (patient-driven iCBT) and 28 to the control

condition (standard iCBT). We had to end the data collection at 56 participants, since running the RCT was costly and we did not have resources to continue. One participant never answered the pre-assessment measurement forms, so data analyses are based on a total of 55 participants.

#### 2.4. Interventions

The internet-delivered treatment programs used in this study for both treatment groups were developed by Livanda-Internetkliniken AB. The treatment programs target different mental health problems including anxiety, worry, stress, sleep problems, and depression, and each program consists of eight modules. The programs include text selections, video and audio clips, exercises, and home assignments offering psychoeducation about symptoms and evidence-based tools for dealing with various mental disorders. The tools presented are based on principles cognitive behavioral therapy (CBT) and acceptance and commitment therapy (ACT), such as exposure, acceptance, valued action, mindfulness, and defusion. The structure of all Livanda's programs is basically the same. The conceptualization can look different depending on the problem in focus (anxiety, worry, stress, depression or sleep problems), but the strategies, content and approach are very much alike. In the current randomized controlled study, the structure of the treatment programs is the constant, i.e. equal in both conditions, and it is the choices that vary between conditions. See Appendix.

# 2.4.1. The experimental condition: patient-driven iCBT

Participants randomized to the experimental condition were asked during the randomization call to choose different elements of the treatment. The procedure for selecting treatment was the following. The therapist presented the possible programs that were available, anxiety, worry, stress and exhaustion, sleep and depression. Once the participant had selected the program, the therapist presented the modules in the program and the overall content in them to the patient. The therapist then informed about choices in the treatment. The participant could choose which program he/she wanted to complete, how many modules he/she wanted to complete (between 2 and 8 modules), which modules he/she wanted to complete and in which order the modules are to be activated in the treatment platform. The participant then chose whether the tempo should be a module that is activated during the week or every other week. The participant also chose how much telephone contact they wished with their therapist (maximum one call every other week and mandatory one follow-up call by the end of the treatment) and if they wished weekly written feedback from their therapist (or otherwise made contact themselves when necessary). The calls took about an hour.

# 2.4.2. The control condition: standard iCBT

Participants randomized to the control condition received the standard iCBT program for anxiety disorders at the participating unit (which were the same treatment program targeting anxiety described for patient-driven iCBT). Hence, the standard iCBT was healthcare staff controlled, tailored by psychologists by letting the diagnosis guide the treatment choices. The treatment program is a transdiagnostic program aimed at treating people with mild to moderate anxiety problems and consists of eight modules. Participants were given a new module each week and were expected to complete the treatment within 8 weeks. The therapist provided weekly written feedback on the participants' exercises and interacted with the participants through secure encrypted messages in the treatment program. A follow-up telephone call took place in the middle of treatment (by module 4) and at the end of the treatment (after module 8).

# 2.5. Measurements

# 2.5.1. MINI version 7.0.1

(Mini International Neuropsychiatric Interview; Sheehan et al.,

1998) is a structured diagnostic interview that assesses criteria for the most common psychiatric disorders based on DSM-IV or ICD-10.

#### 2.5.2. Patient-control over treatment

As a complement to assess more specific care-oriented questions regarding empowerment and influence on care, a questionnaire where the participant estimates their perceived impact on treatment content and scope, support, structure and length was developed by the researchers for this study. The questionnaire aimed to measure patients' perceptions of how much they had been able to control the treatment. The present study alpha was 0.877. The questionnaire consists of seven items answered on a 7-point scale, with answers ranging from 1 (Not at all) to 7 (Very much). Examples of questions were: "How much impact do you feel you had on the treatment plan in general?" and "How much impact do you feel you had on your contact with the therapist?" Scores for the first five questions were totaled, with higher scores indicating perceptions of more control over the treatment. Participants were also asked, "Did you want to have more influence/control over the treatment structure?" (measured on a 7-point scale from 1 = "I influenced/ controlled just enough" to 7 = "I wanted to influence/control more") and "Would you have liked the therapist to have controlled the treatment structure more?" (measured on a 7-point scale from 1 = "The therapist influenced/controlled just enough" to 7 = "I wanted to influence/control more"). The last two questions were analyzed separately. Participants also had the opportunity to provide optional feedback on how the treatment could have been more patient-driven.

#### 2.5.3. Adherence to treatment

Was measured by counting the completed modules in the treatment program for each participant. The digital platform used in the current study allowed tracking of participants activity in the treatment. A completed module constituted of reading all the texts, watch videos and listening to audio files.

# 2.5.4. The empowerment scale

(Making Decisions Scale; Rogers et al., 1997) is a self-assessment scale constructed to measure perceptions of empowerment. The scale consists of 28 items answered on a 4-point Likert scale. Scores range from 28 to 112. Higher scores indicate a stronger sense of empowerment.

### 2.5.5. GAD-7

(Generalized Anxiety Disorder 7-item scale; Spitzer et al., 2006) is a well-established self-assessment scale that measures symptoms of worry/anxiety. The scale consists of seven items, and scores range from 0 to 21, with higher scores indicating more anxiety symptoms. There are thresholds for mild ( $\geq$ 5), moderate ( $\geq$ 10), and severe ( $\geq$ 15) anxiety.

# 2.5.6. MADRS-S

(Montgomery Åsberg Depression Rating Scale; Montgomery and Åsberg, 1979) is a self-assessment scale that measures symptoms of depression. The instrument consists of nine items. Scores range from 0 to 54 with higher scores indicating more depressive symptoms. There are cut-off points for symptom absent (0–6), mild (7–19), moderate (20–34) and severe (>34) depression.

# 2.5.7. WHODAS 2.0

(The WHO Disability Assessment Schedule–12-item version; Rehm et al., 1999) is a self-assessment scale of general disability. Scores range from 12 to 60, with higher scores indicating higher disability. The instrument has established normative data.

# 2.5.8. A COVID-19 questionnaire

Developed for this study measured participant's perceptions of how much they had been affected by the COVID-19 pandemic. The questionnaire consists of seven items answered on a 7-point scale with answers ranging from 1= Very much for the worse, through 4= not at all/not relevant, to 7= Very much for the better. Questions included "How has your mental health been affected by the COVID-19 pandemic?" and "How have your social relationships been affected by the COVID-19 pandemic?"

#### 2.6. Data analysis

The data analysis was performed in IBM SPSS Statistics 25. An independent t-test was performed to assess between-group differences in perceived control over the treatment. Difference in adherence to treatment was assessed by descriptive statistics and by percentage of completed modules between the groups, as well as by the non-parametric Mann–Whitney U test.

The analyses for the outcome measures of anxiety symptoms, depression, general disability, and empowerment included all participants who were randomized, according to the intention-to-treat principle. Continuous outcomes variables measured pre, post and at 3-month follow-up were analyzed using repeated linear mixed models with an unstructured covariance structure to test the overall change over time in the patient-driven condition and the interaction between the two groups and time, where time was included as a factor (pre, mid, post, and follow-up). Each model's overall interaction effect was tested, as well as the interactions from pre to each of the following timepoints. Both within-group and between-group effect sizes (Cohen's *d*) were calculated on observed data (Cohen, 1988).

Correlations between empowerment and severity of anxiety symptoms were analyzed by comparing changes in perceived empowerment and changes in anxiety symptoms from pre to post assessment using Pearson correlation coefficients. All correlation analyses were based on actual values.

To estimate the effect of the COVID-19 pandemic on participants' daily life, the COVID-19 questionnaire used in this study was analyzed using descriptive statistics dividing participants who felt they had been affected for the better from those who felt that they had been affected for the worse and calculating a mean value for each group. Correlation analysis using Spearman's rho  $(\rho)$  was used to investigate correlations between being affected by the pandemic and their anxiety symptoms at the 3-month follow-up for the group who had been affected for the worse, since the variable was found to be non-normally distributed between the two groups.

# 3. Results

There was a difference between the two treatment conditions in their use of antidepressant medication with 17 participants (60.7%) in the control condition using medication compared with 8 participants (29.6%) in the experimental condition. There was however no association between change in anxiety from pre to post and the use of medication. ( $X^2[1] = 14.01$ , P = .592, R = .592).

Table 2 shows descriptive statistics for all the measurement points for the outcome variables of empowerment, anxiety, depression, and general disability.

### 3.1. Choices made

Table 3 summarizes the choices made by the participants in the patient driven experimental group.

# 3.2. Effects of treatment

# 3.2.1. Control over treatment

The results from the independent t-test for perception of control over the treatment for the first five questions on the questionnaire showed a statistically significant difference between groups (t[43] = 2.13, p = .04, n = 45). The first five questions on the questionnaire, where higher

Table 2

Descriptive statistics for the outcome variables Empowerment Scale. GAD-7, MADRS-S and WHODAS

Variable	Patient-driven iCBT Mean (SD) N = 27		Standard iCBT Mean (SD) <i>N</i> = 28	
Empowerment scale		N		N
Pre	77.07 (8.4)	27	73.39 (9.1)	28
Middle	77.79 (8.2)	14	75.06 (8.3)	18
Post	82.95 (7.2)	22	74.48 (9.5)	23
3 Month follow up	83.35 (5.8)	23	76.52 (9.5)	25
GAD-7				
Pre	12.33 (5.2)	27	12.50 (5.1)	28
Middle	7.80 (5.0)	15	10.11 (4.3)	19
Post	5.23 (3.9)	22	9.30 (5.3)	23
3 Month follow up	5.65 (4.6)	23	7.08 (4.2)	26
MADRS-S				
Pre	19.30 (8.3)	27	21.79 (9.1)	28
Middle	12.64 (6.6)	14	18.39 (9.2)	18
Post	9.82 (6.7)	22	17.30 (10.4)	23
3 Month follow up	10.35 (5.6)	23	13.88 (9.0)	25
WHODAS				
Pre	13.14 (8.9)	22	15.40 (7.5)	25
Middle	11.08 (6.3)	13	12.83 (6.6)	18
Post	8.00 (7.9)	22	12.91 (8.2)	23
3 Month follow up	7.43 (5.2)	23	11.84 (9.8)	25
Control over treatmen	t			
Post	24.00 (7.3)	21	18.83 (8.9)	23

**Table 3** Participants choices regarding the treatment structure (intervention group, N = 27)

Choices		
Treatment program	Anxiety	18
Frequencies (%)		(67)
	Worry	7 (26
	Stress	1 (4)
	Sleep problems	1 (4)
	Depression	0 (0)
Number of modules in the	8 (whole program)	25
treatment program	7	(93)
Frequencies (%)	7–0	2 (7)
		0 (0)
Order of modules	Standard order of modules	23
		(85)
Frequencies (%)	Customized order of modules	4 (15
Treatment rate	New module every week	24
		(89)
Frequencies (%)	New module every other week	3 (11
Contact with therapist		
Telephone contact	By middle and by end of treatment	9 (33
Frequencies (%)	(standard)	14
	By every other module	(52)
	No contact	2 (7)
	Other (2 respectively 3 times during	2 (7)
	treatment period)	
Written contact	Yes	24
		(89)
Frequencies (%)	No	3 (11

scores indicate perceptions of more control over the treatment, scored a mean of 24.00 (SD 7.3) in the experimental condition compared with 18.83 (SD 8.9) in the control condition. On the question, "Did you want to have more influence/control over the treatment structure?" where lower scores indicated perceptions of enough influence and where higher scores indicated a stronger wish for more influence, the experimental group scored a mean of 2.59 compared with the control group's mean score of 3.91. On the question, "Would you have liked the therapist to have controlled the treatment structure more?" the experimental group scored a mean of 2.68 and the control condition scored a mean

score of 3.61, where lower scores indicated a wish for stronger therapist control and where higher scores indicated wanting more influence oneself.

#### 3.2.2. Adherence to treatment

One participant was lost to follow-up regarding adherence to treatment. Twelve participants (48%) in the patient-driven experimental condition completed all the treatment modules compared with 14 (50%) in the standard condition. Participants in the patient-driven condition completed a median value of 3.5 modules (min 0 – max 8) in the treatment program compared to the participants in the control group who completed a median value of 5.5 modules (min 0 – max 8). Mann–Whitney U test showed no statistical difference between groups with regards to completed modules (U = 404, P = .48, N = 54). Table 4 shows the percentage of completed modules for each treatment condition.

# 3.2.3. Anxiety, depression, general disability and empowerment

According to the linear mixed models, each continuous outcome showed a significant improvement over time in the patient-driven condition; Empowerment scale (df = 38.2; F = 7.3; p = .001), GAD-7 (df = 45.0; F = 29.9; p < .001), MADRS-S (df = 40.1; F = 26.8; p < .001), and WHODAS (df = 40.1; F = 11.1; p < .001). However, as can be seen in Table 5, only generalized anxiety, measured with GAD-7, showed an overall interaction effect between the two conditions, where the patient-driven condition had a significantly larger reduction in GAD-7 at the post-measurement. Otherwise, no time x group interactions were significant.

At a three-month follow up participants in the patient-driven iCBT showed larger reduction of symptoms with between-group effects of  $d=0.33\,$  for anxiety symptoms,  $d=0.47\,$  for depression and  $d=0.56\,$  for general disability, for observed values.

Since participants filled-in their measurements immediately after they made their own choices (in the experimental patient-driven iCBT) or not (in the standard iCBT) we did additional independent t-tests on absolute values at every measurement point for the Empowerment scale. On the first measuring occasion the results for the difference in mean scores between the groups was not significant. We expected it to take a little longer for the choices to actually affect the participants' context and before it would make a difference in treatment and outcome. The difference in mean scores on the Empowerment scale between the groups was significant on the post measuring occasion (t[43] = 3.36, p = .002, n = 45). With a mean value of 82.95 (7.2) in the experimental patient-driven condition and 74.48 (9.5) in the standard iCBT. The difference in mean scores on the Empowerment scale between the groups was also significant on the 3-month follow-up measuring occasion (t[43] = 2.962, p = .005, n = 45). With a mean value of 83.35 (5.8) in the experimental patient-driven condition and 76.52 (9.5) in the standard iCBT, and with a large between-group effect size (d = 0.86) for observed values (Fig. 1).

# 3.3. Associations between empowerment and outcome

The Pearson's coefficient correlation analysis showed a medium but significant correlation between pre- to post changes in empowerment and anxiety scores for both groups combined (r=-0.47, p=.001, n=

**Table 4** Adherence to treatment.

Percentage of modules completed	Patient-driven iCBT, $N = 26^{a}$	Standard iCBT, N = 28	Total
Less than 25%	8 (31%)	6 (21%)	14
25-50%	5 (19%)	5 (18%)	10
50-75%	1 (4%)	3 (11%)	4
75–100%	12 (46%)	14 (50%)	26

<sup>&</sup>lt;sup>a</sup> 1 participant was lost for follow-up.

Table 5 Linear Mixed Models tests of the two conditions differences in change over time (i.e. group  $\times$  time interaction) for repeatedly measured outcomes.

Interaction effects at each time point compared to pre-treatment			Group*time-interaction (omnibus test)
MID Estimate p	POST Estimate p	FU Estimate p	
-0.595 $p = .640$	3.238 $p = .082$	3.143 p = .110	
-2.389 $p = .083$	-3.904 p = .007		
-2.273 $p = .152$	-3.505 $p = .051$	-0.752 $p = .691$	$\begin{aligned} p &= .038 \\ df &= 40.1 \\ F &= 2.097 \end{aligned}$
0.522 $p = .789$	-2.173 p = .154		
	point com MID Estimate p -0.595 p = .640 -2.389 p = .083 -2.273 p = .152 0.522	point compared to pre-  MID POST Estimate Estimate p p  -0.595 3.238 p = .640 p = .082  -2.389 -3.904 p = .083 p = .007  -2.273 -3.505 p = .152 p = .051  0.522 -2.173	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$

45). Rerunning the analysis comparing the two treatment conditions showed a small non-significant relationship between changes in empowerment and anxiety scores between start and end of treatment for the patient-driven experimental group (r=-0.17, p=.44, n=22) and a strong, statistically significant relationship for the control group (r=-0.62, p=.002, n=23).

#### 3.4. Questions regarding COVID-19

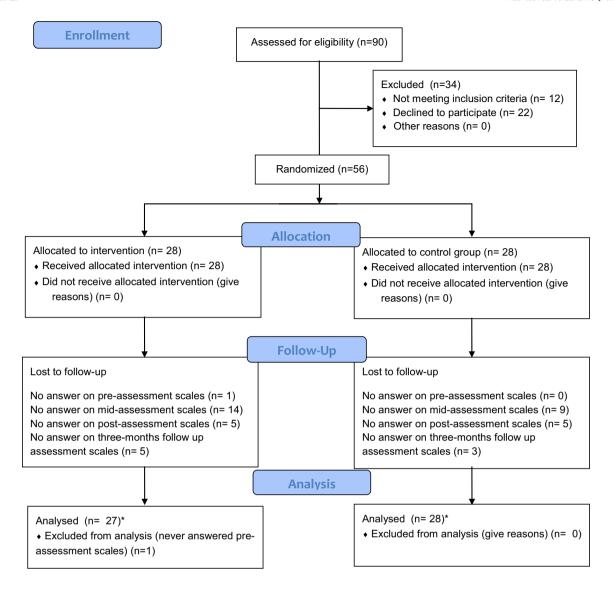
Participants were asked to rate whether and how much they had been affected by the COVID-19 pandemic on 7-point scale ranging from 1= Very much for the worse to 7= Very much for the better, with 4= not at all/not relevant. Of the 37 participants who answered the question, 27 (73%) reported being affected for the worse, 8 (22%) for the better, and 2 (5%) said they had not been affected at all or the question was not relevant. The mean score of those stating they had been affected for the worse was 3.30 and of those stating they had been affected for the better was 4.54. The mean score for all 37 participants was 3.60, indicating a minimal overall effect of the pandemic.

Correlation analysis with Spearman's rho ( $\rho$ ) for those stating they had been affected for the worse showed a weak non-significant correlation between being affected by the pandemic and their anxiety symptoms at the 3-month follow-up ( $\rho = 0.17$ , p = .41, n = 27).

# 4. Discussion

The aim of this RCT was to explore the effect of making the iCBT-treatment more patient-driven, by letting participants choose between broad alternatives in therapy. The experimental condition consisting of patient-driven iCBT was compared to standard iCBT tailored by psychologists by letting the diagnosis guide the treatment choices and having a set number of modules in treatment. The study also aimed to explore patients' experience of empowerment and its potential association with treatment outcomes for anxiety.

The results showed that, at the end of treatment, participants in the patient-driven experimental group had statistically significant higher perceptions of their ability to control their treatment than the group receiving standard iCBT. Moreover, participants in the control group scored higher than the patient-driven group on the two questions asking whether they would have liked to have more influence over their treatment, with higher scores indicating wanting more influence. As previously described, the participants in the patient-driven experimental group were able to choose among a broad series of choices to compass their own tailored treatment, including scope and content of focus in the treatment program as well as choices regarding formats such as length of treatment. All participants met the diagnostic criteria for an



\*The exact number of participants varied in the different analyses.

Fig. 1. CONSORT flow diagram \*The exact number of participants varied in the different analyses.

anxiety disorder based on the diagnostic interview M.I.N.I. and the majority (67%) in the patient-driven condition chose the anxiety treatment program, while 26% chose the program aimed at worry. Regarding the remaining choices, the participants in the patient-driven condition made small choices regarding treatment length, and order of modules, none of which resulted in much difference from the standard iCBT treatment offered in routine primary care. The choices that differed most from standard treatment were contact with therapist (over half wanted more frequent contact) and more time to complete the treatment (about 10%). Even though the choices made by the participants in the experimental condition, did not differ much from the standard procedures, the experience of having the opportunity to choose had an effect on the perception of the ability to control treatment.

There were significant improvements in anxiety, depression, and general disability in both groups. However, only generalized anxiety showed an interaction effect between the two conditions, where participants in the patient-driven experimental condition had a significantly larger reduction of symptoms. Patients with anxiety disorders were the target-population and the results show that letting patients with anxiety drive the treatment might have a greater effect on the

primary problem of anxiety, than using standard iCBT. Other studies have shown that accommodating patient treatment can influence treatment outcomes (Adamson et al., 2008; Mergl et al., 2011; Williams et al., 2016). Taking patients preferences into account has been associated with higher completion of treatment, and higher improvement in clinical outcomes (Lindhiem et al., 2014; Swift et al., 2018).

In the current study, there were no differences in adherence between the two groups. A possible reason for the lack of difference between the two groups could be that some patients might have needed more information and discussion of the choice of treatment target/program in the experimental group to increase the power and strength in the design. The researchers were careful not to influence the patient's choices by answering to many questions or assisting in choices between treatments, since the groups then would have been more similar (in the control condition the professional decided which program etc. to use). Future studies should use more comprehensive, objective information for patients in the patient-driven experimental condition to explore the effect more fully in outcomes.

The current study also explored patients' experience of empowerment and its potential association with treatment outcomes for anxiety.

The concept of empowerment revolves around believing in oneself, one's self-worth and power in life. The opportunity to influence treatment and adapt treatment to own preferences was expected to increase the experience of empowerment during the treatment. The results from the main analysis showed no significant interaction effect between time and treatment condition on empowerment. Participants in the experimental condition were able to choose treatment elements before the premeasurements, before the treatment started. We expected the effect of choices to manifest during the treatment, and that the largest part of variance would be observed here, but the immediate effect of choosing might be stronger than we expected and the boost in empowerment before pre- measurements might have made the room for later change smaller. Future studies should measure empowerment before participants choose treatment modules.

The results showed a significant medium association between changes in anxiety symptoms and changes in empowerment, indicating that participants who had improved the most in empowerment also decreased the most in anxiety symptoms and vice versa, patients who improved the most in anxiety improved the most in empowerment. The association was stronger in the standard iCBT condition. The overall effect on empowerment in both conditions can be understood in the light of the knowledge that Internet-based therapies inherently promote patients as active agents of their own care, and giving patients control in some areas may be a functionally important pathway toward positive treatment outcomes. In addition, the ACT-influenced CBT intervention used in both arms in the current study promotes living according to identified values, with goals and strategies developed to enhance patients' active agency in creating their own lives. These aspects of treatment could very well be a good fit with the patient-driven components. Empowerment as a mechanism of change can provide useful information and insight into how to improve future interventions for example by letting the patients' voice and preferences be elevated. Fostering patient empowerment, as opposed to focusing solely on symptom reduction, might therefore be a crucial component of health promotion. Since the definition of primary care focuses on empowering individuals treated by professionals, it is important to find ways to have patients feel that they have control and influence in their contact with primary care. The result of the current study regarding the effect on perceived control in the experimental patient-driven condition, indicates that placing the patient behind the wheel in digital contacts might be fruitful for fulfilling the goal for primary care of strengthening the patient's experience of influencing and controlling treatment in their journey to recovery. However, the findings regarding the process of perceived control and empowerment and its role in treatment outcomes should be interpreted with caution and further investigated in larger studies.

There are limitations to the present study. One weakness is that the study is under-powered. Replication of these findings in larger randomized controlled studies are thus needed. The participants in the patient-driven experimental condition were asked to make several choices with regards to the treatment structure. Regarding the choice of treatment content, the majority of participants in the patient-driven group chose the anxiety program, and thus there was no major difference between groups regarding which treatment program they completed. Although the more factors that can be influenced hypothetically may contribute to a higher control over the treatment, another limitation is that we cannot draw conclusions about which of the choices, if any, were more significant for the outcome than others. Also, it is important to underscore that the current study cannot separate effects that are caused by the act of choosing in itself, from effects due to the consequences of these choices. For example, the participants in the patient-driven experimental group could choose which treatment program, targeting various mental health problems (such as anxiety, worry, stress, sleep disorders and depression) they wanted access to, while all participants in standard iCBT were given access to the anxiety program. In theory, this choice might have caused better effect on anxiety symptoms by giving the patient an increased sense of control or

empowerment, which in turn could affect behaviors, thoughts, and emotion, as well as by leading to the patient being exposed to other, and for them overall more beneficial, therapeutic content and methods. These, or other possible mechanism or causal pathways, for example the frequency in receiving new modules, cannot be separated from each other with the current study design. Moreover, the questionnaire on patient-control did not allow participants to indicate that they might have felt that they had too much control over the treatment, which potentially might be an interesting aspect for investigation in future studies.

Despite its limitations, some strengths of the study can be mentioned. The standard iCBT-group controlled for non-specific effects of patientdriven treatments. Hence, the standard condition is under control and easily followed and described. Furthermore, the study was conducted in routine primary care, in which the participants were recruited from the natural patient flow, and thus represented a clinical group. Eligible participants sought treatment for mental ill health at their primary care health center. General practioners (GPs), or psychologist made a first assessment of somatic and psychiatric symptoms and then referred patients to the central unit for iCBT. The sample in the current study showed clinical characteristics common for the primary care setting and the most common psychiatric diagnosis was the unspecified anxiety disorder, representing 48% of the sample. Generalized anxiety disorder, panic disorder and health anxiety were also common in the sample and mirror the general primary care setting well. Almost 67% of the participants had previous experiences of psychological treatment and about 37% had ongoing psychopharmacological treatment. Thus, patients were not recruited via advertisement. The results thus can be seen as more generalizable to the clinical setting.

# 4.1. COVID-19

During the course of this study, the world was affected by the COVID-19 pandemic. Some study participants had already been recruited previous to the pandemic start, but the majority of participants for this study were recruited during the pandemic. Early research suggests that the pandemic has affected people in many different ways, including their mental state. Because the pandemic may have influenced the participants, and therefore the results, we asked how much participants felt it had affected them in areas such as their mental and physical health, their social relationships, their economic and work situations, and their trust in authorities and healthcare. The participants' mean value on the COVID-19 questionnaire indicates that most participants felt they hadn't been much affected. However, the therapists' clinical impression was that some participants had a hard time executing parts of the treatment such as to expose themselves to anxiety-provoking situations or doing things in line with their valued direction (which are main mechanisms in reducing fear and anxiety in many CBT and ACTprotocols), since those situations might be at odds with the Swedish Public Health Agency's recommendations for reducing the spread of the virus. Moreover, some participants said that they felt better during the pandemic since they weren't naturally exposed to anxiety-provoking situations due to the recommendations of for example avoiding social gatherings.

# 4.2. Conclusion

Results indicate that iCBT that is to a larger extent patient-driven, may have a greater effect on anxiety, than standard iCBT. The effect on perceived control over treatment might also be larger in patient-driven treatments than in standard iCBT. Empowerment increased in both groups over time. Internet-based therapies inherently promote patients as active agents of their own care and might be well suited for promoting perceived control and empowerment. Findings need to be replicated given the small sample size and the explorative nature of the study.

#### **Declaration of competing interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix 1. Treatment modules in Livanda, control condition standard iCBT n=28, experimental condition patient-driven iCBT n=27

Anxiety Program (patient-driven iCBT $n=18$ , standard iCBT $n=28$ )	Stress Program (patient-driven iCBT $n=7$ )	$\begin{array}{l} \mbox{Depression Program} \\ \mbox{(patient-driven iCBT } n = 0) \end{array}$	Worry Program (patient-driven iCBT $n=7$ )	Sleep program (patient-driven iCBT $n=1$ )
Modul 1: CBT: -Introduction and information on anxiety and normalityAnxiety behavior analysis.	Modul 1: CBT: -Introduction and information on stress and normality. -Stress analysis (energy balance)	Modul 1: CBT: -Information about depression and normality. -Depression analysis -Rational for behavior activation. -Mood diary	Modul 1: CBT: -Introduction and information on anxiety, worry and normality. -Worry analysis	Modul 1: CBT: -Introduction and information on sleep and sleep problems. -Sleep diary
ACT: Personal values and goal setting (ACT).	ACT: Personal values and goal setting	ACT: Personal values and goal setting	ACT: Personal values and goal setting	
Modul 2: CBT: -Principles of learning and motivation -Behavior analysis	Modul 2: CBT: -Motivational tool -Continuing analysis of energy balance -Exposure for calming and self-caring behaviors ACT: Reflections on choices	Modul 2: CBT: -Motivational tool -Reflections on excessive and deficit behaviors. -Behavioral activation -Mood diary.	Modul 2: CBT: -Worry analysis	SKILL: Applied relaxation – part 1 Modul 2: CBT: -Rational sleep restriction and stimulus control -Scheduling bedtime pattern -Sleep diary
SKILL: Applied relaxation – part 1 Modul 3: CBT: -Exposure training -Behavior analysis	SKILL: Applied relaxation – part 1  Modul 3: CBT: -Exposure training -Behavior analysis of stress behaviors -Information about reinforcement principles.	Modul 3: CBT: -Exploring avoidance -Motivational tool – using rewards -Behavioral activation	ACT: -Control exercises -Postponing rumination  Modul 3: CBT: -Reflections on excessive and deficit behaviors -Exposure training	SKILL: Applied relaxation – part 2 Modul 3: CBT: -Methods for falling asleep -Scheduling bedtime pattern -Sleep diary
ACT: Reflections on choices				ACT: Handling thoughts
SKILL: Applied relaxation – part 2  Modul 4: CBT: -Behavior analysis and exposure training	SKILL: Applied relaxation – part 2  Modul 4: CBT: -Behavior analysis of stress behaviors -Information of sleep	Modul 4: CBT: -Behavioral activation	SKILL: Applied relaxation – part 1 Modul 4: CBT: -Exposure training -In-depht behavior analysis	SKILL: Applied relaxation – part 3  Modul 4: CBT: -Handling thoughts -Scheduling bedtime pattern -Sleep diary (continued on next page

# (continued)

(continued)				
Anxiety Program (patient-driven iCBT $n = 18$ , standard	$\begin{array}{l} \text{Stress Program} \\ \text{(patient-driven iCBT } n = 7) \end{array}$	$\begin{array}{l} \mbox{Depression Program} \\ \mbox{(patient-driven iCBT } n = 0) \end{array}$	Worry Program (patient-driven iCBT $n = 7$ )	Sleep program (patient-driven iCBT $n=1$ )
iCBT n = 28)				
	improvement.			
ACT: -Experiental exercises on control -Postponing rumination	ACT: -Experiental exercises on defusion -Exposure training focusing on defusion. SKILL:	ACT: -Experiental exercises on control -Postponing rumination	ACT: -Reflections on choices	
SKILL: Applied relaxation – part 3	Applied relaxation – part 3		SKILL: Applied relaxation – part 2	SKILL:
Modul 5: CBT: -Experiental exercises on defusionExposure training focusing on defusion	Modul 5: CBT: -Continuing behavior analysis of stress behaviors -Exposure for anti-stress behaviors ACT: -Experiental exercises on control -Postponing rumination -Metaphoric reflections on	Modul 5: CBT: -Behavioral activation  ACT: -Experiental exercises on	Modul 5: CBT: -Continuing behavior analysis - Exposure training focusing on defusion.  ACT: -Experiental exercises on defusion	Applied relaxation – part 4 Modul 5 -Stress and sleep -Behavior analysis on stress behaviors and sleep -Sleep hygiene -Scheduling bedtime pattern -Sleep diary
	values and direction  SKILL:  Applied relaxation – part 4	defusion.	SKILL: Applied relaxation - part 3	
SKILL: Applied relaxation – part 4 Modul 6: CBT: -Information about emotions and feelings Exposure training focusing on feelings.	Modul 6: CBT: -Continuing behavior analysis of stress behaviors -Exposure	Modul 6: CBT: -Information about emotions and feelings. -Exposure training focusing on feelings. (i.e. positive feelings) -Behavioral activation	Modul 6: CBT: -Information about emotions and feelings -Exposure training focusing on feelings	Modul 6: CBT: -Scheduling bedtime pattern -Sleep diary
ACT: -Metaphoric reflections on values and direction.		ACT: Metaphoric reflections on values and direction.	ACT: Metaphoric reflections on values and direction	ACT: -Experiental exercises on defusionExperiental exercises on controlling thoughts -Metaphoric reflections on values and direction.
	SKILL:		SKILL: Applied relaxation - part 4	
Modul 7: SKILL: Mindfulness training Modul 8: CBT: Maintenance planning	-Assertiveness training -Communication training -Problem solving -Time management Modul 7: SKILL: Mindfulness training Modul 8: CBT: Maintenance planning	Modul 7: SKILL: Mindfulness training Modul 8: CBT: Maintenance planning	Modul 7: SKILL: Mindfulness training Modul 8: CBT: Maintenance planning	Modul 7: SKILL: Mindfulness training Modul 8: CBT: Maintenance planning

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