

Chatbot ELME for Everyday Life Mindfulness Experience: The effects of a chatbot-based intervention on stress and health-related parameters in a stressed sample

Christine Schillings, Dominik Meißner, Benjamin Erb, Eileen Bendig, Dana Schultchen, Olga Pollatos

Submitted to: JMIR Mental Health
on: July 01, 2023

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript..... 5

Supplementary Files..... 35

 Figures 36

 Figure 1..... 37

 Figure 2..... 38

 Figure 3..... 39

 Multimedia Appendixes 40

 Multimedia Appendix 41

Chatbot ELME for Everyday Life Mindfulness Experience: The effects of a chatbot-based intervention on stress and health-related parameters in a stressed sample

Christine Schillings¹ MSc; Dominik Meißner² MSc; Benjamin Erb² Dr. rer. nat.; Eileen Bendig³ DPhil; Dana Schultchen¹ DPhil; Olga Pollatos¹ DPhil, MD

¹Department of Clinical and Health Psychology Institute of Psychology and Education Ulm University Ulm DE

²Institute of Distributed Systems Ulm University Ulm DE

³Department of Clinical Psychology and Psychotherapy Institute of Psychology and Education Ulm University Ulm DE

Corresponding Author:

Christine Schillings MSc

Department of Clinical and Health Psychology

Institute of Psychology and Education

Ulm University

Albert-Einstein-Allee 43

Ulm

DE

Abstract

Background: Stress levels and the prevalence of mental disorders in the general population have been rising in recent years. Chatbot-based interventions represent novel and promising digital approaches to improve health-related parameters. However, there is a lack of research on chatbot-based interventions in the area of mental health.

Objective: The present study investigated the effects of a three-week chatbot-based intervention guided by the chatbot ELME, aiming to reduce stress and to improve various health-related parameters in a stressed sample.

Methods: In this multicenter, two-armed randomised controlled trial, 118 individuals with a medium to high stress levels were randomised to the intervention group (n = 59) or to a treatment-as-usual control group (n = 59). Chatbot ELME guided participants of the intervention group through three weeks of training based on the topics stress, mindfulness and interoception with practical and psychoeducative elements with two daily interactive intervention sessions via smartphone (à 10-20 min.). The primary outcome perceived stress and secondary outcomes mindfulness, interoception (interoceptive sensibility), psychological well-being, and emotion regulation (subfacets reappraisal and suppression) were assessed pre-intervention (t1), post-intervention (t2; after three weeks), and follow-up (t3; after six weeks). During both conditions, participants also underwent ecological momentary assessments of stress and interoceptive sensibility.

Results: There were no significant changes in perceived stress ($\eta^2 = .018$; SE = .329; $p = .956$) and momentary stress. Mindfulness and the subfacet reappraisal significantly increased due to the intervention over time. Interoceptive sensibility and the subfacet suppression did not change; well-being increased in both groups. Momentary interoceptive sensibility increased in both groups over time.

Conclusions: To the best of our knowledge, the present study is the first chatbot-based intervention integrating contents of the health-related parameters stress, interoception, and mindfulness in an interactive format which provides a flexible use in everyday life. To gain insight into how the intervention can be improved to achieve its full potential for stress reduction, moderating and mediating variables could be examined. Clinical Trial: The trial is registered at the WHO International Clinical Trials Registry Platform via the German Clinical Trials Register (DRKS00027560; date of registration: 06 January 2022).

(JMIR Preprints 01/07/2023:50454)

DOI: <https://doi.org/10.2196/preprints.50454>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

Please make my preprint PDF available to anyone at any time (recommended).

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

✓ **Only make the preprint title and abstract visible.**

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible to all users.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <http://www.jmir.org/preprint/50454>



Original Manuscript

Chatbot ELME for Everyday Life Mindfulness Experience: The effects of a chatbot-based intervention on stress and health-related parameters in a stressed sample



Abstract

Background: Stress levels and the prevalence of mental disorders in the general population have been rising in recent years. Chatbot-based interventions represent novel and promising digital approaches to improve health-related parameters. However, there is a lack of research on chatbot-based interventions in the area of mental health.

Objective: The present study investigated the effects of a three-week chatbot-based intervention guided by the chatbot ELME, aiming to reduce stress and to improve various health-related parameters in a stressed sample.

Methods: In this multicenter, two-armed randomised controlled trial, 118 individuals with a medium to high stress levels were randomised to the intervention group ($n = 59$) or to a treatment-as-usual control group ($n = 59$). Chatbot ELME guided participants of the intervention group through three weeks of training based on the topics stress, mindfulness, and interoception with practical and psychoeducative elements in two daily interactive intervention sessions via smartphone (á 10-20 min.). The primary outcome perceived stress and secondary outcomes mindfulness, interoception (interoceptive sensibility), subjective well-being, and emotion regulation (subfacets reappraisal and suppression) were assessed pre-intervention (t1), post-intervention (t2; after three weeks), and follow-up (t3; after six weeks). During both conditions, participants also underwent ecological momentary assessments of stress and interoceptive sensibility.

Results: There were no significant changes in perceived stress ($\beta_{03} = -.018$; $SE = .329$; $p = .956$) and momentary stress. Mindfulness and the subfacet reappraisal significantly increased due to the intervention over time. The subfacet suppression did not change. Well-being and momentary interoceptive sensibility increased in both groups over time.

Conclusions: To gain insight into how the intervention can be improved to achieve its full potential for stress reduction, besides a longer intervention duration, specific samples should be considered. The chatbot-based intervention seems to have the potential to improve mindfulness and emotion regulation in a stressed sample. Future chatbot-based studies and interventions in health care should be designed based on the latest previous findings on the efficacy of rule-based and AI-based chatbots.

Trial registration: The trial is registered at the WHO International Clinical Trials Registry Platform via the German Clinical Trials Register (DRKS00027560; date of registration: 06 January 2022).

Key words: chatbot, intervention, stress, interoception, interoceptive sensibility, mindfulness, emotion regulation

Background

Stress levels and the prevalences of mental disorders in the general population have been rising in recent years and accelerated by the COVID-19 pandemic [1]. Digital mindfulness-based interventions were indicated as promising approaches to improve mental health outcomes such as stress (e.g., 5–7), mindfulness (e.g., 5,6), or subjective well-being (e.g., 6), highlighting the crucial role of emotion regulation [8]. Thereby, guided online interventions are of high relevance, as they showed higher adherence rates compared to unguided interventions [11–14]. Novel digital approaches of increasing interest include the support by chatbots [15–17] which can be used anonymously, regardless of time and location, and easily integrated in individuals' everyday lives [11,20–23].

Considering chatbot-based interventions aiming to improve mental health outcomes, there is evidence for decreases in distress [27,30–32] or increased subjective and psychological well-being [30,33,34]. Importantly, randomised controlled trials in the context of mental health are sparse and inconsistent [17,19,32,39,40] and there is still a lack of research in the efficacy of chatbot-based interventions [19,32,39], in particular, for emotion regulation and interoception [41,42]. Due to the facts of impaired interoceptive abilities in mental disorders (e.g., 55,56) or long-term stress [47], to train interoceptive abilities is essential, e.g., via mindfulness-based interventions (e.g., 57,58).

To summarize, there is a need for research on chatbot-based interventions respecting diverse characteristics and guidelines. Furthermore, so far, interoception was not in the focus of previous research on chatbot-based interventions, neither as intervention contents nor implemented as ecological momentary assessment (EMA) measures. EMA represents a flexible approach to measure real-time data, e.g. health data, in everyday life [61]. Therefore, we developed a new chatbot-based intervention fostering the abilities interoception, mindfulness, and stress management in everyday life.

The aim of the present study was to investigate the effects of a 3-week chatbot-based intervention on stress, mindfulness, interoception, subjective well-being, and emotion regulation in individuals with medium to high stress levels. Therefore, and based on the described previous findings, perceived stress was chosen as a primary outcome. Further details are described in the study protocol of the present study [67].

We hypothesized that

- 1) the primary outcome perceived stress will be reduced in the intervention group compared to the treatment as usual control group over time – as assessed at pre-, post-intervention and follow-up and via EMA.
- 2) the secondary outcomes mindfulness, interoception (interoceptive sensibility), subjective well-being, and emotion regulation will be improved in the intervention group compared to the control group – as assessed at pre-, post-intervention and follow-up. Momentary interoceptive sensibility and stress was also assessed via EMA.

Furthermore, adherence, dropout reasons, usability, and user feedback regarding the intervention were assessed, to potentially further improve the intervention for future research.

Methods and Analysis

Setting and recruitment

The data collection took place between February and September 2022. German speaking people were recruited via offline and online recruitment strategies. As an incentive, participants could take part in the intervention for free and received the chance to win a € 25 gift card from an online shop or, as a student participant, to receive 5 course credits as

expense allowance for completing the questionnaires. A further incentive was the possible access to two relaxing exercises and to get individual summaries regarding the change in the participants' health-related parameters in the from pre- to follow-up intervention after completing the t3 questionnaire. Participants were included into the study if they (a) were 18 years or older, (b) had sufficient knowledge of the German language, (c) owned a smartphone (Android or iOS) with internet access, (d) possessed a valid smartphone number, (e) possessed a valid mail address, (f) experienced a middle to high perceived stress (PSS-10 score ≥ 14 , assessed at t0), (g) were not diagnosed with any mental disorder, (h) did not undertake psychotherapy, and (i) did not currently participate in another mental health online-intervention.

Study design

The intervention group conducted a three-week online-based intervention guided by the chatbot ELME. The control group received treatment as usual, i.e., no content and just answered the questionnaires and the ecological momentary assessments. Primary and secondary outcomes were assessed in both groups at screening (t0), pre-intervention (t1), daily during the intervention (between t1 and t2), post-intervention (t2), as well as follow-up three weeks after t2 (t3). The design of the present study and the usability of the chatbot were successfully tested in a previous feasibility study. The trial was registered a priori at the WHO International Clinical Trials Registry Platform via the German Clinical Studies Trial Register (DRKS00027560; date of registration: 06 January 2022). The detailed design of the present two-armed, parallel randomised controlled trial is presented in the study protocol [67].

Study procedure

Figure 1 represents the study procedure including the final numbers of participants.

*** Insert Figure 1 ***

Figure 1. Flow chart of the study procedure.

Intervention

ELME is a rule-based chatbot, implemented as a web-based mobile application. ELME offered psychoeducation, exercises in real-time dialogues with the chatbot, audio files, and individual feedback. Sessions were held twice a day (à 10–20 min) over three weeks and with flexible timing. Participants could postpone exercises and receive SMS reminders. For more detailed intervention information and the detailed procedure see descriptions in the study protocol [67]. Exemplary dialogues of the interaction with the chatbot and a participant are depicted in Figures 2 and 3.

*** Insert Figures 2 and 3 ***

Figures 2 and 3. Sample dialogues of the chatbot interacting with a participant (in German language).

Outcome assessment

Primary Outcome: Perceived Stress

The 10-item Perceived Stress Scale (PSS-10; 85) was used as a screening questionnaire. At t1 to t3, perceived stress was assessed via the 4-item short scale (PSS-4). The ratings on both scales ranging from 0 = "never" to 4 = "very often" were calculated as sum scores with higher scores representing higher perceived stress.

Secondary outcomes

Mindfulness

The 14-item short version of the Freiburg Mindfulness Inventory (FMI; 86) was used to assess mindfulness. Answers were rated on the 4-point Likert scale ranging from 1 = “rarely” to 4 = “almost always”. A sum score (range: 14-56) was calculated with higher scores indicating higher mindfulness.

Interoceptive sensibility

Interoceptive sensibility was measured by German versions of the Interoceptive Accuracy Scale (IAS; 87) and the subscale “Awareness” of the Body Perception Questionnaire (BPQ; 88). The 21-item IAS was rated on a 5-point Likert scale ranging from 1 = “disagree strongly” to 5 = “strongly agree”. Higher sum scores (range: 21-105) indicate greater interoceptive sensibility. The subscale “Awareness” of the BPQ consists of 45 items, rated on 5-point Likert scale ranging from 1 = “never” to 5 = “always”.

Subjective well-being

The 5-item WHO Well-Being Index (WHO-5; 89; 90) was used to assess subjective well-being. Participants responded on a 5-point Likert scale ranging from 5 = “all of the time” to 0 = “at no time”. A total sum score (range: 0-100; 100 = best well-being) was calculated from raw scores (range: 0-25) and multiplied with 4.

Emotion regulation

The German version [91] of the Emotion Regulation Questionnaire [92] was used to assess emotion regulation. The 10-item questionnaire included 6 items representing the emotion regulation strategy reappraisal and 4 items assessing the emotion regulation strategy suppression, rated on a 7-point Likert scale ranging from 1 = “strongly disagree” to 7 = “strongly agree”. Accordingly, the mean scores reflect the use of and preferences for the emotion regulation strategies.

Ecological Momentary Assessment

Momentary perceived stress and momentary interoceptive sensibility were measured via ecological momentary assessments twice a day (in the morning and in the afternoon). Momentary perceived stress was assessed via two adapted items for the momentary use of the Perceived Stress Scale Short form (PSS-4; 85): “Do you feel that things are going your way?” and “Do you find you can cope with all the things that you have to do?”. The items “How present do you feel at the moment?” and “How aware are you of your own body at the moment?” [57,66] measured body awareness. To assess interoceptive sensibility, we used a self-developed question, taking the heartbeat perception task by Schandry (1981) into account: “How intense do you perceive your heartbeat in the moment?” aiming at interoceptive sensibility. All rating scales were presented as visual analogue scales ranging from 0 “= not at all” to 100 = “very much”.

Mental Health App Usability Questionnaire

To assess the usability of the chatbot as a mental health App, a self-translated German version of the 18-item Mental Health App Usability Questionnaire (MAUQ; 93) was used, rated on a scale ranging from 1 = “strongly agree” to 7 = “strongly disagree”. The questionnaire comprises the three subscales „ease of use“ (5 items), „interface and satisfaction“ (7 items) and „usefulness“ (6 items). Mean scores for each subscale were calculated as a total mean score with lower mean scores reflecting higher usability.

Adherence, potential dropout reasons and user feedback

Adherence to the intervention was operationalized by the percentage of completed modules of the intervention. Reasons for potential dropout reasons were assessed via the Dropout Reasons Questionnaire for Internet Interventions [94]. User feedback questions asking the participants if they liked the training (range: 1-10) and judging the extent of the training (1 = too short; 12 = too long) were assessed.

Data analysis

Data analyses were conducted according to the intention-to-treat principle. Due to the nested longitudinal data structure, hierarchical linear regression models were calculated to investigate the intervention effects over time. The measurement points (level 1) were nested within the participants (level 2). The regression analyses include the three measurement points pre-intervention (T1), post-intervention (T2) and follow-up (T3). We analysed hierarchical linear models and model comparisons in R using the packages lme4 [95], lmerTest [96] and r2mlm [97]. The predictor variable time had an interpretable zero point and the dichotomous predictor group was dummy-coded. Due to assumed interindividual and intraindividual differences in all outcome variables, random intercept and random slopes models were calculated. The Restricted Maximum Likelihood estimator was applied for parameter estimation, as it is generally considered as less biased compared to the maximum likelihood estimation [98]. In this manuscript, the main results are reported to answer the research questions 1) and 2). The significance level for all analyses was $p \leq .05$.

Results

A total sample of $N = 118$ was randomised to the intervention group ($n = 59$, 72 % female) and to the control group ($n = 59$, 81 % female). The relevant descriptive statistics at T1 depicted in Table 1. There were no significant differences between the groups at T1.

Table 1. Relevant descriptive statistics at T1.

	Intervention group ($n = 59$) Mean (SD)	Control group ($n = 59$) Mean (SD)	$t(116)$	p
Age	33.117 (11.778)	33.085 (13.853)	-.014	.989
Perceived stress	8.017 (2.701)	7.627 (2.355)	-.836	.405
Mindfulness	34.271 (5.825)	34.051 (6.957)	.187	.852
IS (IAS)	82.220 (10.992)	80.475 (9.233)	-.934	.352
IS (BPQ)	3.252 (.793)	3.305 (.561)	.443	.658
Well-being	41.153 (17.341)	42.780 (17.297)	.510	.611
Emotion regulation - reappraisal	4.130 (1.139)	4.429 (.934)	1.561	.121
Emotion regulation - suppression	3.725 (1.260)	3.339 (1.227)	-1.684	.095

Note. SD, standard deviation; BMI, body mass index; IS, interoceptive sensibility; IAS, Interoceptive Accuracy Scale; BPQ, Body Perception Questionnaire.

Perceived stress

Table 3. Random intercept and random slope model for perceived stress with the predictors time, group, and the interaction of time and group.

		Model				
		β	SE	df	t	p
Fixed effects						
Level 1	Intercept	8.135	.337	122.119	24.141	< .001***
	Time	-.341	.222	141.471	-1.538	.126
	Group	.172	.478	123.037	.359	.720
	Cross-level-interaction Time*group	-.018	.329	140.501	-.055	.956
		σ^2	SD			
Random effects (Variance components)						
	σ^2_{u0j} (Intercept)	3.243	1.801			
	σ^2_{u01j} (Time)	.017	.132			
	σ^2_{rij} (Residual)	3.916	1.979			

Note. β = fixed effect coefficients; σ^2 = variance of random effect coefficients; SE = standard errors; SD = standard deviations.

According to the model regarding perceived stress, the non-significant fixed effect of the level-1-predictor time ($\beta_{01} = -.341$; $SE = .222$; $p = .126$) indicates that the stress levels did not change over time (from T1 to T3). The fixed effect of the level-2-predictor group ($\beta_{02} = .172$; $SE = .478$; $p = .720$) and the cross-level-interaction of the variables time and group ($\beta_{03} = -.018$; $SE = .329$; $p = .956$) were not significant. The results of the two models predicting momentary perceived stress showed neither significant effects of time and group nor significant interactions (see Tables A1 and A2).

Mindfulness

Table 4. Random intercept and random slope model for mindfulness with the predictors time,

group, and the interaction of time and group.

		Model				
		β	<i>SE</i>	<i>df</i>	<i>t</i>	<i>p</i>
Fixed effects						
Intercept	Level 1	34.362	.826	115.647	41.589	< .001***
	Level 2					
	Time	.078	.350	68.640	.223	.842
	Group	-.080	1.170	116.058	-.069	.945
Cross-level-interaction						
	Time*group	1.130	.521	71.363	2.171	.033*
		σ^2	<i>SD</i>			
Random effects (Variance components)						
	σ^2_{u0j} (Intercept)	31.906	5.649			
	σ^2_{u01j} (Time)	.113	.336			
	σ^2_{rij} (Residual)	9.461	3.076			

Note. β = fixed effect coefficients; σ^2 = variance of random effect coefficients; *SE* = standard errors; *SD* = standard deviations.

The results of the model regarding mindfulness showed no significant fixed effects time ($\beta_{01} = .078$; *SE* = .350; *p* = .842) and group ($\beta_{02} = -.080$; *SE* = 1.170; *p* = .945). However, the cross-level-interaction of time and group ($\beta_{03} = 1.130$; *SE* = .521; *p* = .033) was significant.

Interceptive Sensibility

The results of the model predicting interoceptive sensibility (assessed via the Interoceptive Accuracy Scale) revealed neither significant effects of time and group nor a significant interaction (see Table A3). Similarly, assessments via the Body Perception Questionnaire showed no significant effects (see Table A4.)

Momentary IS increased on average by $\beta_{01} = .229$ (*SE* = .076; *p* = .003) from measurement point to measurement point in both groups. The effects for group and the cross-level-interaction of time and group were not significant (see Table A5).

Well-being

Table 5. Random intercept and random slope model for well-being with the predictors time,

group, and the interaction of time and group.

		Model				
		β	<i>SE</i>	<i>df</i>	<i>t</i>	<i>p</i>
Fixed effects						
Intercept	Level 1	42.150	2.236	115.591	18.848	< .001***
	Level 2					
	Time	4.237	1.479	74.662	2.865	.005**
	Group	-.032	3.168	116.363	-.010	.992
Cross-level-interaction						
	Time*group	2.312	2.189	78.034	1.056	.294
		σ^2	<i>SD</i>			
Random effects (Variance components)						
	σ^2_{u0j} (Intercept)	185.17	13.608			
	σ^2_{u01j} (Time)	26.580	5.156			
	σ^2_{rij} (Residual)	124.180	11.144			

Note. β = fixed effect coefficients; σ^2 = variance of random effect coefficients; *SE* = standard errors; *SD* = standard deviations.

Subjective well-being improved over time in both groups on average by $\beta_{01} = 4.237$ (*SE* = 1.479; *p* = .005). There were neither significant differences in the groups ($\beta_{02} = -.031$; *SE* = 3.168; = .992) nor significant changes over both time and group ($\beta_{03} = 2.312$; *SE* = 2.189; *p* = .294).

Emotion regulation – subfacet reappraisal

Table 6. Random intercept and random slope model for emotion regulation, subfacet reappraisal, with the predictors time, group, and the interaction of time and group.

		Model				
		β	<i>SE</i>	<i>df</i>	<i>t</i>	<i>p</i>
Fixed effects						
	Intercept	4.426	.133	116.328	33.297	< .001***
Level 1						
	Time	.022	.064	127.10	.347	.729
Level 2						
	Group	-.255	.188	116.819	-1.353	.179
	Cross-level-interaction					
	Time*group	.223	.096	127.085	2.331	.021*
		σ^2	<i>SD</i>			
Random effects (Variance components)						
	σ^2_{u0j} (Intercept)	.775	.880			
	σ^2_{u01j} (Time)	.006	.075			
	σ^2_{rij} (Residual)	.302	.550			

Note. β = fixed effect coefficients; σ^2 = variance of random effect coefficients; *SE* = standard errors; *SD* = standard deviations.

The results of the model concerning the subfacet reappraisal of emotion regulation revealed neither a significant effect of time ($\beta_{01} = .022$; *SE* = .064; *p* = .729) nor of group ($\beta_{02} = -.255$; *SE* = .188; *p* = .179). The cross-level-interaction of time and group ($\beta_{03} = .223$; *SE* = .096; *p* = .021) was significant.

Emotion regulation – subfacet suppression

Results regarding the subfacet suppression of emotion regulation revealed no significant changes (see Table A6).

Adherence, dropout reasons and user feedback

The mean adherence was 58 % ($n = 59$). $n = 23$ skipped intervention units; as the main reason for skipping intervention units, time reasons were reported ($n = 19$). Separately, $n = 22$ reported technical problems. The answer rates of the EMA questions are 48 % on average in the intervention group and 66 % in the control group. The overall rating of the question if the participants liked the training was 6.95 ($SD = 1.86$). The extent of the training was rated with 7.62 on average.

Usability

The mean usability (total score) was 2.55 ($SD = .68$), with means of the subscales „ease of use“ $M = 1.85$ ($SD = 1.01$), „interface and satisfaction“ $M = 2.62$ ($SD = 1.08$), and „usefulness“ $M = 3.2$ ($SD = .94$).

Discussion**Principal Results**

The present study aimed to examine the effects of a three-week chatbot-based intervention on perceived stress and various health-related parameters in stressed individuals. Results show no significant changes in perceived stress. There was a significant increase in mindfulness and in emotion regulation as assessed by the subfacet reappraisal in the intervention group over time. The subfacet suppression did not change. Well-being and momentary interoceptive sensibility increased in both groups over time.

Comparison with Prior Work***Effects on perceived stress***

The non-significant reduction in perceived stress is in line with the findings of similar intervention studies by 99 and the pilot study by 34; 99, however, considering statistical power problems of these studies. The intervention duration or intensity might be one factor for interpreting the missing effects of the present study. Another explanation could be that, at first, there might be a higher focus on stress perception and potentially buffering stress reducing effects due to the intervention. This approach is supported by findings due to psychotherapeutic interventions [101,102] showing the assumed effects on psychological outcomes later because of the confrontation with emotionally charging topics. Furthermore, such as the results by 103 and 104 indicate, the effects on perceived stress might become (more) visible after a longer duration of the intervention.

The results regarding momentary perceived stress are in line with studies based on 3-month mindfulness-based interventions [63,64]. Moreover, the mean adherence regarding the present intervention of 58 %, the mean answer rates of the EMA questions need to be considered when interpreting the results.

Effects on mindfulness

The significant increase in mindfulness is in line with previous findings due to online mindfulness-based interventions (e.g., 6; 5), indicating that the 3-week chatbot-based intervention comprising mindfulness-based contents has the potential to increase mindfulness over time in a stressed sample. A possible mechanism might be that the contents of the intervention addressing mindfulness, stress, and interoception support mindfulness. Nevertheless, mindfulness needs to be interpreted as a secondary outcome in the present study.

Effects on interoceptive sensibility

The missing effects are contrary to previous positive effects on interoceptive abilities due to diverse mindfulness-based interventions (e.g., 57; 105; 58). However, these effects were found in the context of interventions lasting at least eight weeks. In particular and in line with the present findings, a one-week mindfulness-based intervention [58] or a 3-week heartbeat perception training [60] could not improve interoceptive abilities. The present findings support the approach by 105, 57, and 60 supposing that to improve interoceptive abilities, a longer intervention might be necessary. Moreover, previous studies differ in their methods to assess diverse dimensions of interoceptive abilities (e.g., 43,106). Last but not least, a longer intervention design of the present, innovative intervention might be only reasonable after first trials with a shorter intervention design like the duration of three weeks in the present study. Due to the innovative EMA questions of the present study and another study design not including an intervention, results are not comparable to the previous EMA study by 65. The significant increase in momentary interoceptive sensibility could be explained by a training effect of frequent EMA which took place twice a day over three weeks.

Effects on emotion regulation

In line with the results regarding reappraisal, in a recent systematic review and meta-analysis on mental health apps to promote emotion regulation and positive mental health in the general population [107], a medium effect of $g = .49$ was reported for emotion regulation compared to control conditions. It needs to be emphasized that this effect is based on only $n = 6$ studies, reflecting that there is still a lack of RCT's on s chatbot-based interventions addressing emotion regulation.

Effects on well-being

The increase in well-being is in line with comparable previous studies [30,33,34,37], considering differences in the study designs and samples. However, well-being in the control group of the present study was also improved, which might be also induced by the daily ecological momentary assessments as potential positive triggers or observational processes.

Strengths and Limitations

To the best of our knowledge, the present study is the first chatbot-based intervention including contents and assessments on interoception, as well as its association with mindfulness and stress. Further strengths of the study are the highly standardized design in line with the CONSORT guidelines [110,111] and ecological momentary assessments of interoceptive sensibility [65,66,112]. Furthermore, the design and the usability of the chatbot were successfully tested in a previous feasibility study. Therefore, the chatbot fulfills the required standards for chatbots for mental health support [11]. Finally, the results could show a high usability of the chatbot.

Limitations of the present study should be mentioned and considered for the design of future studies. Firstly, the adherence of 58 % of the intervention was limited. Nevertheless, this adherence rate is on average as compared to online-mindfulness-based interventions with adherence rates ranging from 35% to 92% [113]. It needs to be noted that adherence rates of digital or chatbot-based interventions were often not reported or operationalised by diverse assessments [32,114] and lacking long-term user engagement in e-Health is a common problem [115,116]. Secondly, 77 % of the participants were female. Therefore, future intervention studies should consider diverse strategies to specifically address male participants. Thirdly, the present study exclusively assessed self-report data. Due to potential

differences to objective physiological data [119], future studies should assess subjective and objective data, especially regarding stress and interoception. Lastly, a text- and rule-based chatbot as used in this study might lack on human appearance regarding, e.g, the type of interaction between the chatbot and the user. Recent meta-analyses [120,121] showed that chatbot-based studies are more effective when diverse input and output modalities are combined.. A multimodal chatbot might be superior because it appears more lively and flexible in dialogues [122] and ready to interact.

Conclusions and Future Research

To gain insight into how the intervention can be improved to achieve its full potential for stress reduction, besides a longer intervention duration, specific samples should be considered, e.g., employees, diverse age groups, clinical or subclinical populations, aiming to adapt to individual needs and preferences in every-day life. The chatbot-based intervention seems to have the potential to improve mindfulness and emotion regulation in a stressed sample. Additional factors such as the participants' social motivation regarding the guidance by the chatbot and the personality of the chatbot [115,123] would be of further interest to foster the alliance or a therapeutic relationship between the user or a patient and the chatbot. Future studies should also investigate in detail which elements such as psychoeducation or exercises have the greatest effects to improve diverse health parameters. Future research should implement large language models to provide and further develop diverse artificially intelligent (AI) chatbots in digital mental health interventions [127,128]. Latest findings like AI-based chatbots being more effective in clinical or subclinical populations [121] need to be considered. Nevertheless, besides the chances of AI-based chatbots for the professional mental health service, emerging reputational risks of AI-based chatbots such as safety and data privacy issues [129,130], gender, ethnical and socio-economic biases [131], limited empathy and emotional awareness as compared to a human counterpart [132] and hallucinations [133] should be discussed extensively. To sum up, based on the numerous chances of chatbots in the psychological and medical field such as counselling, psychotherapy, diagnostic assessment and interventions [19,134,135], future studies are needed to derive robust implications in these fields.

Acknowledgements: We would like to thank all students and student assistants for their contributions in the development of the chatbot, especially, Julia Kegelmann, Sina Gorhan, Ria Matapurkar, Luisa Braitsch, and the further collaboration in the project with Anna-Lena Schäling, Vanessa Runft, Lena Gilbert, and Sandra Hoppe.

Ethics approval and Consent to Participate: All study procedures were approved by the ethics committee of Ulm University (application No. 401/20). Written informed consent was obtained from all participants prior to their participation.

Conflicts of Interest: There are no conflicts of interest.

Funding: This research received no external funding.

Authors' contributions: CS initiated the study. ELME was developed by the Department of Clinical and Health Psychology and the Institute of Distributed Systems at Ulm University (lead developers CS, DM and BE). CS, DM, BE, DS and OP designed and planned the study. EB, DS, BE and OP supervised the study. CS is responsible for the recruitment and the conduction of the study. DM is responsible for the technical implementation of the chatbot. CS wrote the first draft of the manuscript. All authors discussed the results of the study, edited the manuscript and approved the final version of the manuscript.

References

1. Salari N, Hosseini-Far A, Jalali R, Vaisi-Raygani A, Rasoulpoor S, Mohammadi M, Rasoulpoor S, Khaledi-Paveh B. Prevalence of stress, anxiety, depression among the general population during the COVID-19 pandemic: a systematic review and meta-analysis. *Global Health* 2020;16(1):57. PMID:32631403
2. McEwen BS, Eiland L, Hunter RG, Miller MM. Stress and anxiety: structural plasticity and epigenetic regulation as a consequence of stress. *Neuropharmacology* 2012;62(1):3-12. PMID:21807003
3. Ehler U, Gaab J, Heinrichs M. Psychoneuroendocrinological contributions to the etiology of depression, posttraumatic stress disorder, and stress-related bodily disorders: the role of the hypothalamus-pituitary-adrenal axis. *Biol Psychol* 2001;57(1-3):141-152. PMID:11454437
4. Poca B. The ICD-11 has been adopted by the World Health Assembly. *World Psychiatry* 2019;18(3):371-372. PMID:31496092
5. Zhang Y, Xue J, Huang Y. A meta-analysis: Internet mindfulness-based interventions for stress management in the general population. *Medicine (Baltimore)* 2020;99(28):e20493. PMID:32664060
6. Spijkerman MPJ, Pots WTM, Bohlmeijer ET. Effectiveness of online mindfulness-based interventions in improving mental health: A review and meta-analysis of randomised controlled trials. *Clin Psychol Rev* 2016;45:102-114. PMID:27111302
7. Nguyen-Feng VN, Greer CS, Frazier P. Using online interventions to deliver college student mental health resources: Evidence from randomized clinical trials. *Psychol Serv* 2017;14(4):481-489. PMID:29120206
8. Ma Y, She Z, Siu AF-Y, Zeng X, Liu X. Effectiveness of Online Mindfulness-Based Interventions on Psychological Distress and the Mediating Role of Emotion Regulation. *Front. Psychol.* 2018;9:2090. PMID:30429816
9. Goldin PR, Gross JJ. Effects of mindfulness-based stress reduction (MBSR) on emotion regulation in social anxiety disorder. *Emotion* 2010;10(1):83-91. PMID:20141305
10. Gratz KL, Levy R, Tull MT. Emotion Regulation as a Mechanism of Change in an Acceptance-Based Emotion Regulation Group Therapy for Deliberate Self-Harm Among Women With Borderline Personality Pathology. *J Cogn Psychother* 2012;26(4):365-380. doi:10.1891/0889-8391.26.4.365
11. Kretschmar K, Tyroll H, Pavarini G, Manzini A, Singh I. Can Your Phone Be Your Therapist? Young People's Ethical Perspectives on the Use of Fully Automated Conversational Agents (Chatbots) in Mental Health Support. *Biomed Inform Insights* 2019;11:1178222619829083. PMID:30858710
12. Musiat P, Johnson C, Atkinson M, Wilksch S, Wade T. Impact of guidance on intervention adherence in computerised interventions for mental health problems: a meta-analysis. *Psychol Med* 2022;52(2):229-240. PMID:34802474
13. Domhardt M, Geßlein H, Rezori RE von, Baumeister H. Internet- and mobile-based interventions for anxiety disorders: A meta-analytic review of intervention components. *Depress Anxiety* 2019;36(3):213-224. PMID:30450811
14. Ebert DD, Buntrock C, Lehr D, Smit F, Riper H, Baumeister H, Cuijpers P, Berking M. Effectiveness of Web- and Mobile-Based Treatment of Subthreshold Depression With Adherence-Focused Guidance: A Single-Blind Randomized Controlled Trial. *Behav Ther* 2018;49(1):71-83. PMID:29405923
15. Adamopoulou E, Moussiades L. Chatbots: History, technology, and applications. *Machine Learning with Applications* 2020;2:100006. doi:10.1016/j.mlwa.2020.100006
16. Brandtzaeg PB, Følstad A. *Why People Use Chatbots*: Springer International Publishing;

- 2017.
17. Bendig E, Erb B, Schulze-Thuesing L, Baumeister H. Die nächste Generation: Chatbots in der klinischen Psychologie und Psychotherapie zur Förderung mentaler Gesundheit – Ein Scoping-Review. *Verhaltenstherapie* 2019;29(4):266-280. doi:10.1159/000499492
 18. Abdul-Kader SA, Woods JC. Survey on Chatbot Design Techniques in Speech Conversation Systems. *ijacsa* 2015;6(7). doi:10.14569/IJACSA.2015.060712
 19. Bendig E, Erb B, Schulze-Thuesing L, Baumeister H. The Next Generation: Chatbots in Clinical Psychology and Psychotherapy to Foster Mental Health – A Scoping Review. *Verhaltenstherapie* 2019;1-13. doi:10.1159/000501812
 20. Hill J, Randolph Ford W, Farreras IG. Real conversations with artificial intelligence: A comparison between human–human online conversations and human–chatbot conversations. *Computers in Human Behavior* 2015;49:245-250. doi:10.1016/j.chb.2015.02.026
 21. Müschenich M, Wamprecht L. Gesundheit 4.0 – Wie gehts uns denn morgen? [Health 4.0 - how are we doing tomorrow?]. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 2018;61(3):334-339. PMID:29411045
 22. Gamble A. Artificial intelligence and mobile apps for mental healthcare: a social informatics perspective. *AJIM* 2020;72(4):509-523. doi:10.1108/AJIM-11-2019-0316
 23. Stieger M, Nißen M, Rügger D, Kowatsch T, Flückiger C, Allemand M. PEACH, a smartphone- and conversational agent-based coaching intervention for intentional personality change: study protocol of a randomized, wait-list controlled trial. *BMC Psychol* 2018;6(1):43. PMID:30180880
 24. Sebastian J, Richards D. Changing stigmatizing attitudes to mental health via education and contact with embodied conversational agents. *Computers in Human Behavior* 2017;73:479-488. doi:10.1016/j.chb.2017.03.071
 25. Bakker D, Kazantzis N, Rickwood D, Rickard N. Mental Health Smartphone Apps: Review and Evidence-Based Recommendations for Future Developments. *JMIR Ment Health* 2016;3(1):e7. PMID:26932350
 26. D'Alfonso S, Santesteban-Echarri O, Rice S, Wadley G, Lederman R, Miles C, Gleeson J, Alvarez-Jimenez M. Artificial Intelligence-Assisted Online Social Therapy for Youth Mental Health. *Front. Psychol.* 2017;8:796. PMID:28626431
 27. Vaidyam AN, Wisniewski H, Halamka JD, Kashavan MS, Torous JB. Chatbots and Conversational Agents in Mental Health: A Review of the Psychiatric Landscape. *Can J Psychiatry* 2019;64(7):456-464. PMID:30897957
 28. Mitsea E, Drigas A, Skianis C. Digitally Assisted Mindfulness in Training Self-Regulation Skills for Sustainable Mental Health: A Systematic Review. *Behav Sci (Basel)* 2023;13(12). PMID:38131865
 29. Haque MDR, Rubya S. An Overview of Chatbot-Based Mobile Mental Health Apps: Insights From App Description and User Reviews. *JMIR Mhealth Uhealth* 2023;11:e44838. PMID:37213181
 30. Suganuma S, Sakamoto D, Shimoyama H. An Embodied Conversational Agent for Unguided Internet-Based Cognitive Behavior Therapy in Preventative Mental Health: Feasibility and Acceptability Pilot Trial. *JMIR Ment Health* 2018;5(3):e10454. PMID:30064969
 31. Gaffney H, Mansell W, Tai S. Conversational Agents in the Treatment of Mental Health Problems: Mixed-Method Systematic Review. *JMIR Ment Health* 2019;6(10):e14166. PMID:31628789
 32. Vaidyam AN, Linggonegoro D, Torous J. Changes to the Psychiatric Chatbot Landscape: A Systematic Review of Conversational Agents in Serious Mental Illness: Changements du paysage psychiatrique des chatbots: une revue systématique des agents conversationnels dans la maladie mentale sérieuse. *Can J Psychiatry* 2021;66(4):339-348.

PMID:33063526

33. Potts C, Lindström F, Bond R, Mulvenna M, Booth F, Ennis E, Parding K, Kostenius C, Broderick T, Boyd K, Vartiainen A-K, Nieminen H, Burns C, Bickerdike A, Kuosmanen L, Dhanapala I, Vakaloudis A, Cahill B, Macinnes M, Malcolm M, O'Neill S. A multilingual digital mental health and wellbeing chatbot (ChatPal): pre-post multicenter intervention study (Preprint). *J Med Internet Res* 2022. doi:10.2196/43051
34. Ly KH, Ly A-M, Andersson G. A fully automated conversational agent for promoting mental well-being: A pilot RCT using mixed methods. *Internet Interventions* 2017;10:39-46. PMID:30135751
35. Williams R, Hopkins S, Frampton C, Holt-Quick C, Merry SN, Stasiak K. 21-Day Stress Detox: Open Trial of a Universal Well-Being Chatbot for Young Adults. *Social Sciences* 2021;10(11):416. doi:10.3390/socsci10110416
36. Gabrielli S, Rizzi S, Bassi G, Carbone S, Maimone R, Marchesoni M, Forti S. Engagement and Effectiveness of a Healthy-Coping Intervention via Chatbot for University Students During the COVID-19 Pandemic: Mixed Methods Proof-of-Concept Study. *JMIR Mhealth Uhealth* 2021;9(5):e27965. PMID:33950849
37. Bendig E, Erb B, Meißner D, Bauereiß N, Baumeister H. Feasibility of a Software agent providing a brief Intervention for Self-help to Uplift psychological wellbeing ("SISU"). A single-group pretest-posttest trial investigating the potential of SISU to act as therapeutic agent. *Internet Interventions* 2021;24:100377. PMID:33816127
38. Bendig E, Meißner D, Erb B, Weger L, Küchler A-M, Bauereiss N, Ebert D, Baumeister H. Study protocol of a randomised controlled trial on SISU, a software agent providing a brief self-help intervention for adults with low psychological well-being. *BMJ Open* 2021;11(2):e041573. PMID:33558351
39. Laranjo L, Dunn AG, Tong HL, Kocaballi AB, Chen J, Bashir R, Surian D, Gallego B, Magrabi F, Lau AYS, Coiera E. Conversational agents in healthcare: a systematic review. *J Am Med Inform Assoc* 2018;25(9):1248-1258. PMID:30010941
40. Abd-Alrazaq AA, Alajlani M, Alalwan AA, Bewick BM, Gardner P, Househ M. An overview of the features of chatbots in mental health: A scoping review. *International Journal of Medical Informatics* 2019;132:103978. PMID:31622850
41. Khalsa SS, Adolphs R, Cameron OG, Critchley HD, Davenport PW, Feinstein JS, Feusner JD, Garfinkel SN, Lane RD, Mehling WE, Meuret AE, Nemeroff CB, Oppenheimer S, Petzschner FH, Pollatos O, Rhudy JL, Schramm LP, Simmons WK, Stein MB, Stephan KE, van den Bergh O, van Diest I, Leupoldt A von, Paulus MP. Interoception and Mental Health: A Roadmap. *Biol Psychiatry* 2018;3(6):501-513. PMID:29884281
42. Craig AD. How do you feel? Interoception: the sense of the physiological condition of the body. *Nat Rev Neurosci* 2002;3(8):655-666. PMID:12154366
43. Garfinkel SN, Seth AK, Barrett AB, Suzuki K, Critchley HD. Knowing your own heart: distinguishing interoceptive accuracy from interoceptive awareness. *Biol Psychol* 2015;104:65-74. PMID:25451381
44. Schulz A, Vögele C. Interoception and stress. *Front Psychol* 2015;6:993. PMID:26257668
45. Schulz A, Schultchen D, Vögele C. Interoception, Stress, and Physical Symptoms in Stress-Associated Diseases. *European Journal of Health Psychology* 2020;27(4):132-153. doi:10.1027/2512-8442/a000063
46. Maeda S, Ogishima H, Shimada H. Acute cortisol response to a psychosocial stressor is associated with heartbeat perception. *Physiol Behav* 2019;207:132-138. PMID:31095929
47. Schultchen D, Bayer J, Kühnel J, Melchers KG, Pollatos O. Interoceptive accuracy is related to long-term stress via self-regulation. *Psychophysiology* 2019;56(10):e13429. doi:10.1111/psyp.13429
48. Opdensteinen KD, Schaan L, Pohl A, Schulz A, Domes G, Hechler T. Interoception in preschoolers: New insights into its assessment and relations to emotion regulation and

- stress. *Biol Psychol* 2021;165:108166. PMID:34389438
49. Dunn BD, Stefanovitch I, Evans D, Oliver C, Hawkins A, Dalgleish T. Can you feel the beat? Interoceptive awareness is an interactive function of anxiety- and depression-specific symptom dimensions. *Behav Res Ther* 2010;48(11):1133-1138. PMID:20692645
 50. Pollatos O, Gramann K. Attenuated modulation of brain activity accompanies emotion regulation deficits in alexithymia. *Psychophysiology* 2012;49(5):651-658. PMID:22335425
 51. Gibson J. Mindfulness, Interoception, and the Body: A Contemporary Perspective. *Front. Psychol.* 2019;10:2012. PMID:31572256
 52. Weng HY, Feldman JL, Leggio L, Napadow V, Park J, Price CJ. Interventions and Manipulations of Interoception. *Trends Neurosci* 2021;44(1):52-62. PMID:33378657
 53. Todd J, Aspell JE. Mindfulness, Interoception, and the Body. *Brain Sci* 2022;12(6):696. doi:10.3390/brainsci12060696
 54. Lefranc B, Martin-Krumm C, Aufauvre-Poupon C, Berthail B, Trousselard M. Mindfulness, Interoception, and Olfaction: A Network Approach. *Brain Sci* 2020;10(12):921. PMID:33260427
 55. Fischer D, Berberich G, Zaudig M, Krauseneck T, Weiss S, Pollatos O. Interoceptive Processes in Anorexia Nervosa in the Time Course of Cognitive-Behavioral Therapy: A Pilot Study. *Front Psychiatry* 2016;7:199. PMID:28018249
 56. Eggart M, Lange A, Binser MJ, Queri S, Müller-Oerlinghausen B. Major Depressive Disorder Is Associated with Impaired Interoceptive Accuracy: A Systematic Review. *Brain Sci* 2019;9(6). PMID:31174264
 57. Bornemann B, Singer T. Taking time to feel our body: Steady increases in heartbeat perception accuracy and decreases in alexithymia over 9 months of contemplative mental training. *Psychophysiology* 2017;54(3):469-482. PMID:27925645
 58. Parkin L, Morgan R, Rosselli A, Howard M, Sheppard A, Evans D, Hawkins A, Martinelli M, Golden A-M, Dalgleish T, Dunn BD. Exploring the Relationship Between Mindfulness and Cardiac Perception. *Mindfulness* 2014;5(3):298-313. doi:10.1007/s12671-012-0181-7
 59. Meyerholz L, Irzinger J, Witthöft M, Gerlach AL, Pohl A. Contingent biofeedback outperforms other methods to enhance the accuracy of cardiac interoception: A comparison of short interventions. *J Behav Ther Exp Psychiatry* 2019;63:12-20. PMID:30557753
 60. Schillings C, Karanassios G, Schulte N, Schultchen D, Pollatos O. The Effects of a 3-Week Heartbeat Perception Training on Interoceptive Abilities. *Front. Neurosci.* 2022;16. doi:10.3389/fnins.2022.838055
 61. Balaskas A, Schueller SM, Cox AL, Doherty G. Ecological momentary interventions for mental health: A scoping review. *PLOS ONE* 2021;16(3):e0248152. PMID:33705457
 62. Chin B, Lindsay EK, Greco CM, Brown KW, Smyth JM, Wright AGC, Creswell JD. Psychological mechanisms driving stress resilience in mindfulness training: A randomized controlled trial. *Health Psychol* 2019;38(8):759-768. PMID:31120272
 63. Linz R, Puhlmann LMC, Engert V, Singer T. Investigating the impact of distinct contemplative mental trainings on daily life stress, thoughts and affect-Evidence from a nine-month longitudinal ecological momentary assessment study. *Psychoneuroendocrinology* 2022;142:105800. PMID:35598494
 64. Aguilar-Raab C, Stoffel M, Hernández C, Rahn S, Moessner M, Steinhilber B, Ditzen B. Effects of a mindfulness-based intervention on mindfulness, stress, salivary alpha-amylase and cortisol in everyday life. *Psychophysiology* 2021;58(12):e13937. PMID:34525214
 65. Höller I, Stenzel J-S, Rath D, Forkmann T. Listen to Your Heart-Ecological Momentary Assessment of Interoceptive Accuracy, Awareness and Sensibility: A Pilot Study. *Int J Environ Res Public Health* 2021;18(9). PMID:34064438
 66. Singer T, Kok BE, Bornemann B, Zurborg S, Bolz M, Bochow C. The ReSource Project:

- Background, design, samples, and measurements. Second edition; 2016. ISBN:978-3-941504-61-5.
67. Schillings C, Meißner D, Erb B, Schultchen D, Bendig E, Pollatos O. A chatbot-based intervention with ELME to improve stress and health-related parameters in a stressed sample: Study protocol of a randomised controlled trial. *Front. Digit. Health* 2023;5:17. doi:10.3389/fdgth.2023.1046202
 68. Kabat-Zinn J. *Full catastrophe living: using the wisdom of your body and mind to face stress, pain, and illness* /; Bantam Books; 1990. ISBN:0345536932.
 69. Kabat-Zinn J. Mindfulness-Based Interventions in Context: Past, Present, and Future. *Clinical Psychology* 2003;10(2):144-156. doi:10.1093/clipsy/bpg016
 70. Kabat-Zinn J. *Full catastrophe living: Using the wisdom of your body and mind to face stress, pain, and illness*. 2013, revised edition. New York: Bantam Books; 2013. ISBN:0345536932.
 71. Schandry R. Heart Beat Perception and Emotional Experience. *Psychophysiology* 1981;18(4):483-488. doi:10.1111/j.1469-8986.1981.tb02486.x
 72. Kaluza G. *Stressbewältigung: Trainingsmanual zur psychologischen Gesundheitsförderung*. Berlin/Heidelberg: Springer Berlin Heidelberg; 2018. ISBN:9783662440155.
 73. Kaluza G. *Gelassen und sicher im Stress: Das Stresskompetenz-Buch - Stress erkennen, verstehen, bewältigen*. 3., vollst. überarb. Aufl. 2007. Berlin, Heidelberg: Springer Berlin Heidelberg; 2007. ISBN:9783540689003.
 74. Hayes SC, Strosahl KD, Wilson KG. *Acceptance and commitment therapy: An experiential approach to behavior change*. New York: Guilford Press; 1999. ISBN:1572304812.
 75. Hayes SC, Strosahl K, Wilson KG. *Acceptance and commitment therapy: The process and practice of mindful change*. Second edition. New York: The Guilford Press; 2016. ISBN:1462528945.
 76. Küchler A-M, Schultchen D, Pollatos O, Moshagen M, Ebert DD, Baumeister H. StudiCare mindfulness-study protocol of a randomized controlled trial evaluating an internet- and mobile-based intervention for college students with no and "on demand" guidance. *Trials* 2020;21(1):975. PMID:33243300
 77. Schultchen D, Küchler A-M, Schillings C, Weineck F, Karabatsiakakis A, Ebert DD, Baumeister H, Pollatos O. Effectiveness of a guided online mindfulness-focused intervention in a student population: Study protocol for a randomised control trial. *BMJ Open* 2020;10(3):e032775. doi:10.1136/bmjopen-2019-032775
 78. Küchler A-M, Kählke F, Vollbrecht D, Peip K, Ebert DD, Baumeister H. Effectiveness, Acceptability, and Mechanisms of Change of the Internet-Based Intervention StudiCare Mindfulness for College Students: a Randomized Controlled Trial. *Mindfulness* 2022;13(9):2140-2154. doi:10.1007/s12671-022-01949-w
 79. Cameron OG. Interoception: The Inside Story—A Model for Psychosomatic Processes. *Psychosom Med* 2001;63(5):697-710. doi:10.1097/00006842-200109000-00001
 80. Gulliver A, Griffiths KM, Christensen H. Perceived barriers and facilitators to mental health help-seeking in young people: a systematic review. *BMC Psychiatry* 2010;10:113. PMID:21192795
 81. Freeman D, Haselton P, Freeman J, Spanlang B, Kishore S, Albery E, Denne M, Brown P, Slater M, Nickless A. Automated psychological therapy using immersive virtual reality for treatment of fear of heights: a single-blind, parallel-group, randomised controlled trial. *The Lancet Psychiatry* 2018;5(8):625-632. doi:10.1016/S2215-0366(18)30226-8
 82. Huebschmann NA, Sheets ES. The right mindset: stress mindset moderates the association between perceived stress and depressive symptoms. *Anxiety Stress Coping* 2020;33(3):248-255. PMID:32138538

83. Mohr DC, Spring B, Freedland KE, Beckner V, Arean P, Hollon SD, Ockene J, Kaplan R. The selection and design of control conditions for randomized controlled trials of psychological interventions. *PPS* 2009;78(5):275-284. PMID:19602916
84. Guidi J, Brakemeier E-L, Bockting CLH, Cosci F, Cuijpers P, Jarrett RB, Linden M, Marks I, Peretti CS, Rafanelli C, Rief W, Schneider S, Schnyder U, Sensky T, Tomba E, Vazquez C, Vieta E, Zipfel S, Wright JH, Fava GA. Methodological Recommendations for Trials of Psychological Interventions. *Psychotherapy and Psychosomatics* 2018;87(5):276-284. PMID:30007961
85. Cohen S, Kamarck T, Mermelstein R. A Global Measure of Perceived Stress. *Journal of Health and Social Behavior* 1983;24(4):385-396. doi:10.2307/2136404
86. Walach H, Buchheld N, Büttenmüller V, Kleinknecht N, Schmidt S. Measuring mindfulness—the Freiburg Mindfulness Inventory (FMI). *Personality and Individual Differences* 2006;40(8):1543-1555. doi:10.1016/j.paid.2005.11.025
87. Murphy J, Brewer R, Plans D, Khalsa SS, Catmur C, Bird G. Testing the independence of self-reported interoceptive accuracy and attention. *Q J Exp Psychol (Hove)* 2020;73(1):115-133. PMID:31519137
88. Porges SW. Fragebogen zur Körperwahrnehmung 1993 URL: <https://static1.squarespace.com/static/5c1d025fb27e390a78569537/t/5cc07b81ee6eb072574b3620/1556118401872/German+SF+updated+7-17.pdf> [accessed 2019-06-25].
89. World Health Organization. WHO Info Package: Mastering depression in Primary Care; 1998; Frederiksberg.
90. Topp CW, Østergaard SD, Søndergaard S, Bech P. The WHO-5 Well-Being Index: A Systematic Review of the Literature. *Psychotherapy and Psychosomatics* 2015;84(3):167-176. doi:10.1159/000376585
91. Abler B, Kessler H. Emotion Regulation Questionnaire – Eine deutschsprachige Fassung des ERQ von Gross und John. *Diagnostica* 2009;55(3):144-152. doi:10.1026/0012-1924.55.3.144
92. Gross JJ, John OP. Individual differences in two emotion regulation processes: implications for affect, relationships, and well-being. *J Pers Soc Psychol* 2003;85(2):348-362. PMID:12916575
93. Zhou L, Bao J, Setiawan IMA, Saptono A, Parmanto B. The mHealth App Usability Questionnaire (MAUQ): Development and Validation Study. *JMIR Mhealth Uhealth* 2019;7(4):e11500. PMID:30973342
94. Bendig E, Braun L, Simon L. Dropout reasons questionnaire for internet interventions (DRQi) - Questionnaire for the systematic recording of dropout reasons at different stages in the implementation of an online intervention 2020.
95. Bates D, Mächler M, Bolker B, Walker S. Fitting Linear Mixed-Effects Models using lme4; 2014.
96. Kuznetsova A, Brockhoff PB, Christensen RHB. lmerTest Package: Tests in Linear Mixed Effects Models. *J. Stat. Soft.* 2017;82(13). doi:10.18637/jss.v082.i13
97. Rights JD, Sterba SK. Quantifying explained variance in multilevel models: An integrative framework for defining R-squared measures. *Psychol Methods* 2019;24(3):309-338. PMID:29999378
98. Finch WH, Bolin JE, Kelley K. Multilevel modeling using R. Second edition. Boca Raton, London, New York: CRC Press; 2019. ISBN:9781351062251.
99. Gardiner PM, McCue KD, Negash LM, Cheng T, White LF, Yinusa-Nyahkoon L, Jack BW, Bickmore TW. Engaging women with an embodied conversational agent to deliver mindfulness and lifestyle recommendations: A feasibility randomized control trial. *Patient Educ Couns* 2017;100(9):1720-1729. PMID:28495391
100. Maciejewski J, Smoktunowicz E. Low-effort internet intervention to reduce students'

- stress delivered with Meta's Messenger chatbot (Stressbot): A randomized controlled trial. *Internet Interventions* 2023;33:100653. PMID:37575678
101. Schauenburg H, Sammet I, Strack M. Verlauf der Symptombelastung und Vorhersage des Behandlungserfolges in der stationären Psychotherapie. [Course of symptom severity and prediction of outcome in inpatient psychotherapy]. *Z Psychosom Med Psychother* 2001;47(4):380-395. PMID:11731990
 102. Owen J, Adelson J, Budge S, Wampold B, Kopta M, Minami T, Miller S. Trajectories of Change in Psychotherapy. *J Clin Psychol* 2015;71(9):817-827. PMID:26235730
 103. Baer RA, Carmody J, Hunsinger M. Weekly change in mindfulness and perceived stress in a mindfulness-based stress reduction program. *J Clin Psychol* 2012;68(7):755-765. PMID:22623334
 104. Venkatesan A, Krymis H, Scharff J, Waber A. Changes in Perceived Stress Following a 10-Week Digital Mindfulness-Based Stress Reduction Program: Retrospective Study. *JMIR Form Res* 2021;5(5):e25078. PMID:34032571
 105. Fischer D, Messner M, Pollatos O. Improvement of Interoceptive Processes after an 8-Week Body Scan Intervention. *Front Hum Neurosci* 2017;11:452. PMID:28955213
 106. Murphy J, Catmur C, Bird G. Classifying individual differences in interoception: Implications for the measurement of interoceptive awareness. *Psychon Bull Rev* 2019. PMID:31270764
 107. Eisenstadt M, Liverpool S, Infanti E, Ciuvat RM, Carlsson C. Mobile Apps That Promote Emotion Regulation, Positive Mental Health, and Well-being in the General Population: Systematic Review and Meta-analysis. *JMIR Ment Health* 2021;8(11):e31170. PMID:34747713
 108. Guendelman S, Medeiros S, Rampes H. Mindfulness and Emotion Regulation: Insights from Neurobiological, Psychological, and Clinical Studies. *Front. Psychol.* 2017;8:220. PMID:28321194
 109. Gross JJ. Emotion Regulation in Adulthood: Timing Is Everything. *Curr Dir Psychol Sci* 2001;10(6):214-219. doi:10.1111/1467-8721.00152
 110. Eysenbach G. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. *J Med Internet Res* 2011;13(4):e126. PMID:22209829
 111. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010;340:c332. PMID:20332509
 112. Linz R, Puhlmann LMC, Engert V, Singer T. Investigating the impact of distinct contemplative mental trainings on daily life stress, thoughts and affect-Evidence from a nine-month longitudinal ecological momentary assessment study. *Psychoneuroendocrinology* 2022;142:105800. PMID:35598494
 113. Sommers-Spijkerman M, Austin J, Bohlmeijer E, Pots W. New Evidence in the Booming Field of Online Mindfulness: An Updated Meta-analysis of Randomized Controlled Trials. *JMIR Ment Health* 2021;8(7):e28168. PMID:34279240
 114. Beintner I, Vollert B, Zarski A-C, Bolinski F, Musiat P, Görlich D, Ebert DD, Jacobi C. Adherence Reporting in Randomized Controlled Trials Examining Manualized Multisession Online Interventions: Systematic Review of Practices and Proposal for Reporting Standards. *J Med Internet Res* 2019;21(8):e14181. PMID:31414664
 115. Koulouri T, Macredie RD, Olakitan D. Chatbots to Support Young Adults' Mental Health: An Exploratory Study of Acceptability. *ACM Trans. Interact. Intell. Syst.* 2022;12(2):1-39. doi:10.1145/3485874
 116. Torous J, Nicholas J, Larsen ME, Firth J, Christensen H. Clinical review of user engagement with mental health smartphone apps: evidence, theory and improvements. *Evid Based Ment Health* 2018;21(3):116-119. PMID:29871870
 117. König LM, Allmeta A, Christlein N, van Emmenis M, Sutton S. A systematic review

- and meta-analysis of studies of reactivity to digital in-the-moment measurement of health behaviour: Center for Open Science; 2021.
118. Bauhoff S. Systematic self-report bias in health data: impact on estimating cross-sectional and treatment effects. *Health Serv Outcomes Res Method* 2011;11(1-2):44-53. doi:10.1007/s10742-011-0069-3
 119. Zuniga Gonzalez DA, Richards D, Bilgin AA. Making it Real: A Study of Augmented Virtuality on Presence and Enhanced Benefits of Study Stress Reduction Sessions. *International Journal of Human-Computer Studies* 2021;147:102579. doi:10.1016/j.ijhcs.2020.102579
 120. Lim SM, Shiao CWC, Cheng LJ, Lau Y. Chatbot-Delivered Psychotherapy for Adults With Depressive and Anxiety Symptoms: A Systematic Review and Meta-Regression. *Behav Ther* 2022;53(2):334-347. doi:10.1016/j.beth.2021.09.007
 121. Li H, Zhang R, Lee Y-C, Kraut RE, Mohr DC. Systematic review and meta-analysis of AI-based conversational agents for promoting mental health and well-being. *NPJ Digit Med* 2023;6(1):236. PMID:38114588
 122. Montenegro JLZ, da Costa CA, da Rosa Righi R. Survey of conversational agents in health. *Expert Systems with Applications* 2019;129:56-67. doi:10.1016/j.eswa.2019.03.054
 123. Grové C. Co-developing a Mental Health and Wellbeing Chatbot With and for Young People. *Front Psychiatry* 2020;11:606041. PMID:33597898
 124. Dao KP, Cocker K de, Tong HL, Kocaballi AB, Chow C, Laranjo L. Smartphone-Delivered Ecological Momentary Interventions Based on Ecological Momentary Assessments to Promote Health Behaviors: Systematic Review and Adapted Checklist for Reporting Ecological Momentary Assessment and Intervention Studies. *JMIR Mhealth Uhealth* 2021;9(11):e22890. PMID:34806995
 125. Stapleton A, Lavelle JM, McHugh L. Chatbot-delivered acceptance and commitment therapy with adolescents: A pilot randomized controlled trial; 2022.
 126. Schulte-Strathaus JCC, Rauschenberg C, Baumeister H, Reininghaus U. Ecological Momentary Interventions in Public Mental Health Provision. *Digital Phenotyping and Mobile Sensing* 2023;427-439. doi:10.1007/978-3-030-98546-2_25
 127. Thakur S, Rastogi D, Singh L. MOODY: A Natural Language Processing-Based Chatbot for Mental Health Care. In: Mahajan V, Chowdhury A, Padhy NP, Lezama F, editors. *Sustainable Technology and Advanced Computing in Electrical Engineering: Proceedings of ICSTACE 2021*. Vol. 939. 1st ed. 2022. Singapore: Springer Nature Singapore; Imprint Springer; 2022. ISBN:9789811943645. p. 899–908.
 128. Boucher EM, Harake NR, Ward HE, Stoeckl SE, Vargas J, Minkel J, Parks AC, Zilca R. Artificially intelligent chatbots in digital mental health interventions: a review. *Expert Rev Med Devices* 2021;18(sup1):37-49. PMID:34872429
 129. Li J. Security Implications of AI Chatbots in Health Care. *J Med Internet Res* 2023;25:e47551. PMID:38015597
 130. De Freitas J, Uğuralp AK, Oğuz-Uğuralp Z, Puntoni S. Chatbots and mental health: Insights into the safety of generative AI. *J Consum Psychol* 2023. doi:10.1002/jcpy.1393
 131. Kim J, Cai ZR, Chen ML, Simard JF, Linos E. Assessing Biases in Medical Decisions via Clinician and AI Chatbot Responses to Patient Vignettes. *JAMA Netw Open* 2023;6(10):e2338050. PMID:37847506
 132. Pham KT, Nabizadeh A, Selek S. Artificial Intelligence and Chatbots in Psychiatry. *Psychiatr Q* 2022;93(1):249-253. PMID:35212940
 133. Giuffrè M, You K, Shung DL. Evaluating ChatGPT in Medical Contexts: The Imperative to Guard Against Hallucinations and Partial Accuracies. *Clinical Gastroenterology and Hepatology* 2023;0(0). PMID:37863408
 134. Pryss R, Kraft R, Baumeister H, Winkler J, Probst T, Reichert M, Langguth B,

- Spiliopoulou M, Schlee W. Using Chatbots to Support Medical and Psychological Treatment Procedures: Challenges, Opportunities, Technologies, Reference Architecture. In: Digital Phenotyping and Mobile Sensing: Springer, Cham; 2019. p. 249–260.
135. Aggarwal A, Tam CC, Wu D, Li X, Qiao S. Artificial Intelligence-Based Chatbots for Promoting Health Behavioral Changes: Systematic Review. J Med Internet Res 2023;25:e40789. PMID:36826990



Appendix

Momentary perceived stress by ecological momentary assessment, item “coping with things”

Table A1. Random intercept and random slope model for perceived stress (item “coping with things”) as assessed via ecological momentary assessment the predictors time, group, and the interaction of time and group.

		Model				
		β	SE	df	t	p
Fixed effects						
Intercept Level 1		50.592	2.095	104.260	24.148	< .001***
	Time	.033	.065	82.059	.512	.610
	Group	2.696	3.051	111.176	.883	.379
	Cross-level-interaction					
	Time*group	.024	.010	92.408	.240	.811
		σ^2	SD			
Random effects (Variance components)						
	σ^2_{u0j} (Intercept)	211.530	14.544			
	σ^2_{u01j} (Time)	.124	.352			
	σ^2_{rij} (Residual)	244.343	15.632			

Note. β = fixed effect coefficients; σ^2 = variance of random effect coefficients; SE = standard errors; SD = standard deviations.

Momentary perceived stress by ecological momentary assessment, item “feeling on top of things”

Table A2. Random intercept and random slope model for perceived stress (item “feeling on top of things”) as assessed via ecological momentary assessment the predictors time, group, and the interaction of time and group.

		Model				
		β	SE	df	t	p
Fixed effects						
	Intercept	52.364	2.307	102.647	22.699	< .001***
	Level 1					
	Time	-.018	.076	83.131	-.240	.811
	Level 2					
	Group	2.047	3.348	108.395	.061	.542
	Cross-level-interaction					
	Time*group	.084	.115	90.645	.727	.469
		σ^2	SD			
Random effects (Variance components)						
	σ^2_{u0j} (Intercept)	267.685	16.361			
	σ^2_{u01j} (Time)	.211	.459			
	σ^2_{rij} (Residual)	220.839	14.861			

Note. β = fixed effect coefficients; σ^2 = variance of random effect coefficients; SE = standard errors; SD = standard deviations.

Interoceptive sensibility (Interoceptive Accuracy Scale)

Table A3. Random intercept and random slope model for interoceptive sensibility as assessed via the Interoceptive Accuracy Scale with the predictors time, group, and the interaction of time and group.

		Model				
		β	SE	df	t	p
Fixed effects						
	Intercept	80.829	1.256	115.902	64.381	< .001***
	Level 1					
	Time	.268	.692	68.722	.387	.700
	Level 2					
	Group	1.555	1.778	116.575	.875	.384
	Cross-level-interaction					
	Time*group	-.197	1.026	71.524	-.192	.849
		σ^2	SD			
Random effects (Variance components)						
	σ^2_{u0j} (Intercept)	61.135	7.819			
	σ^2_{u01j} (Time)	1.252	1.119			
	σ^2_{rij} (Residual)	36.045	6.004			

Note. β = fixed effect coefficients; σ^2 = variance of random effect coefficients; SE = standard errors; SD = standard deviations.

Interoceptive sensibility (Body Perception Questionnaire)

Table A4. Random intercept and random slope model for interoceptive sensibility as assessed via the Body Perception Questionnaire with the predictors time, group, and the interaction of time and group.

		Model				
		β	<i>SE</i>	<i>df</i>	<i>t</i>	<i>p</i>
Fixed effects						
	Intercept	3.332	.081	115.571	40.974	< .001***
	Level 1					
	Time	.064	.052	61.720	1.220	.227
	Level 2					
	Group	-.057	.115	116.086	-.493	.623
	Cross-level-interaction					
	Time*group	.012	.077	64.980	.156	.877
		σ^2	<i>SD</i>			
Random effects (Variance components)						
	σ^2_{u0j} (Intercept)	.302	.549			
	σ^2_{u01j} (Time)	.056	.237			
	σ^2_{rij} (Residual)	.099	.315			

Note. β = fixed effect coefficients; σ^2 = variance of random effect coefficients; *SE* = standard errors; *SD* = standard deviations.

Momentary interoceptive sensibility

Table A5. Random intercept and random slope model for momentary interoceptive sensibility, with the predictors time, group, and the interaction of time and group.

		Model				
		β	<i>SE</i>	<i>df</i>	<i>t</i>	<i>p</i>
Fixed effects						
	Intercept	37.901	2.477	98.989	15.300	< .001***
Level 1	Time	.229	.076	81.461	3.018	.003**
Level 2	Group	4.551	3.609	104.110	1.261	.210
	Cross-level-interaction					
	Time*group	-.137	.115	90.030	-1.189	.236
		σ^2	<i>SD</i>			
Random effects (Variance components)						
	σ^2_{u0j} (Intercept)	284.540	16.868			
	σ^2_{u01j} (Time)	.158	.397			
	σ^2_{rij} (Residual)	330.894	18.191			

Note. β = fixed effect coefficients; σ^2 = variance of random effect coefficients; *SE* = standard errors; *SD* = standard deviations.

Table A6. Random intercept and random slope model for emotion regulation, subfacet suppression, with the predictors time, group, and the interaction of time and group.

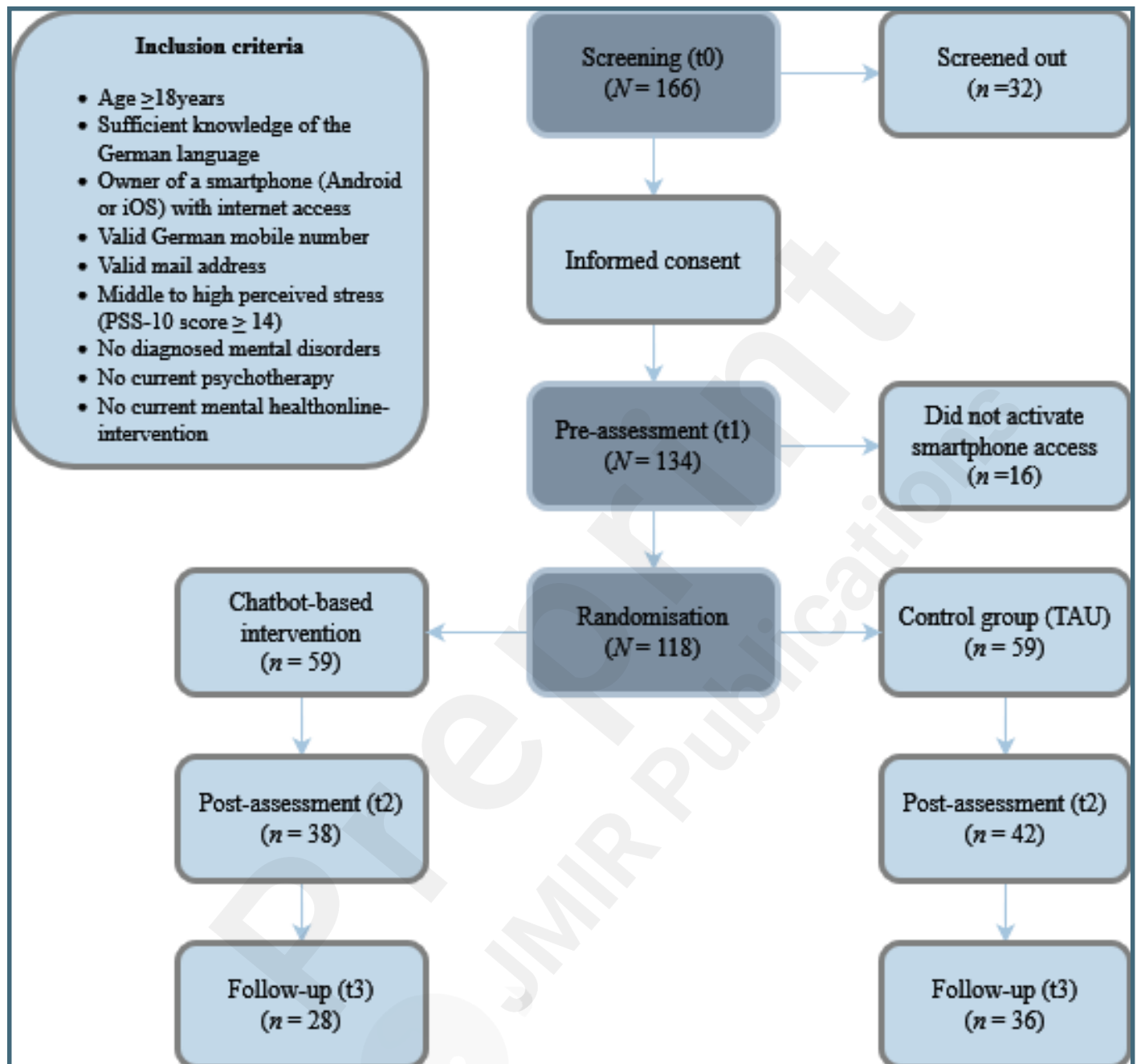
			Model				
			β	SE	df	t	p
Fixed effects							
Fixed effects	Intercept		3.326	.157	114.392	21.239	< .001***
	Level 1						
		Time	-.014	.090	72.059	-.150	.881
	Level 2						
		Group	.404	.222	114.947	1.820	.071
Cross-level-interaction							
		Time*group	-.151	.133	75.692	-1.133	.261
			σ^2	SD			
Random effects (Variance components)							
	σ^2_{u0j} (Intercept)		1.070	1.034			
	σ^2_{u01j} (Time)		.112	.334			
	σ^2_{rij} (Residual)		.425	.652			

Note. β = fixed effect coefficients; σ^2 = variance of random effect coefficients; *SE* = standard errors; *SD* = standard deviations.

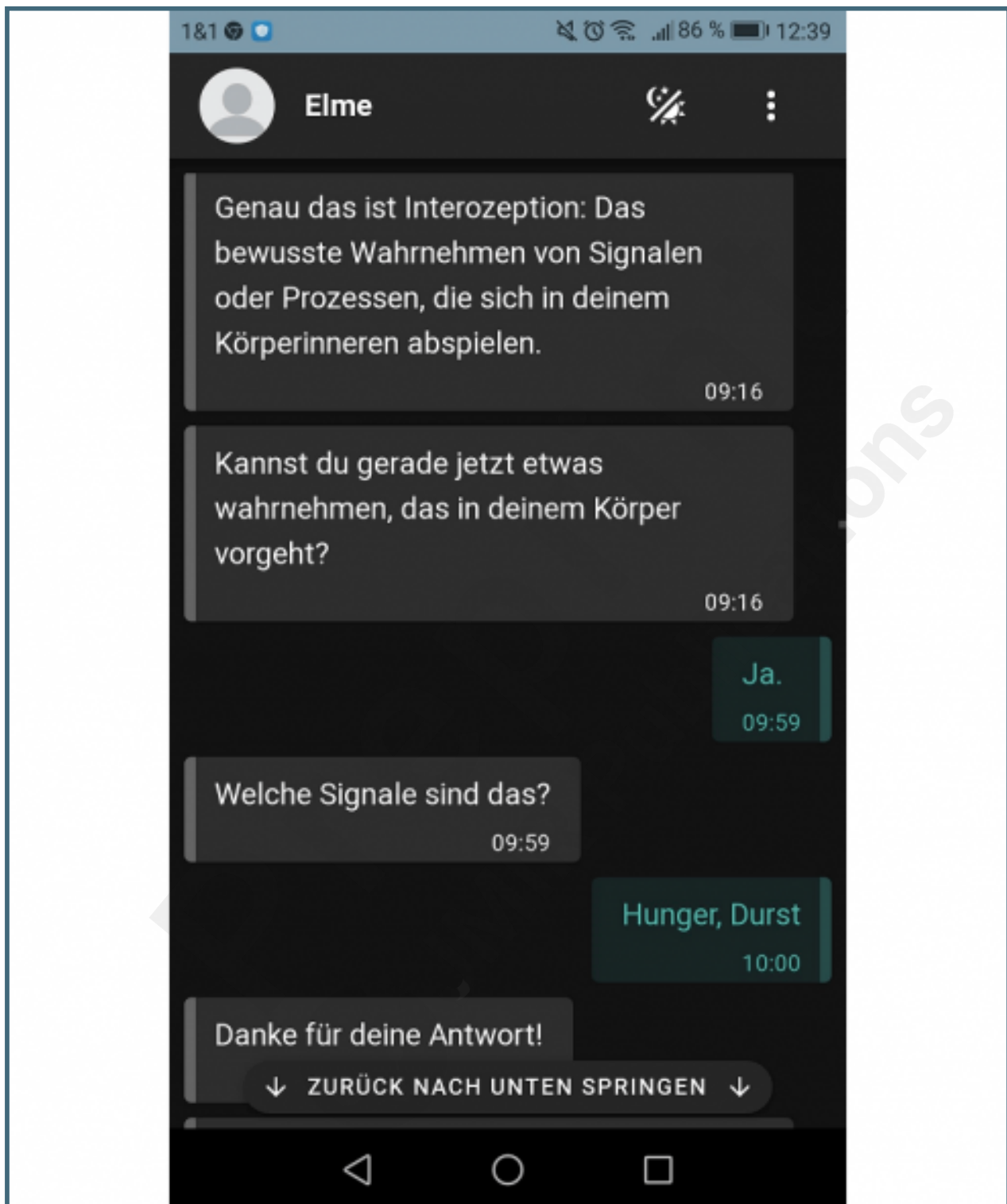
Supplementary Files

Figures

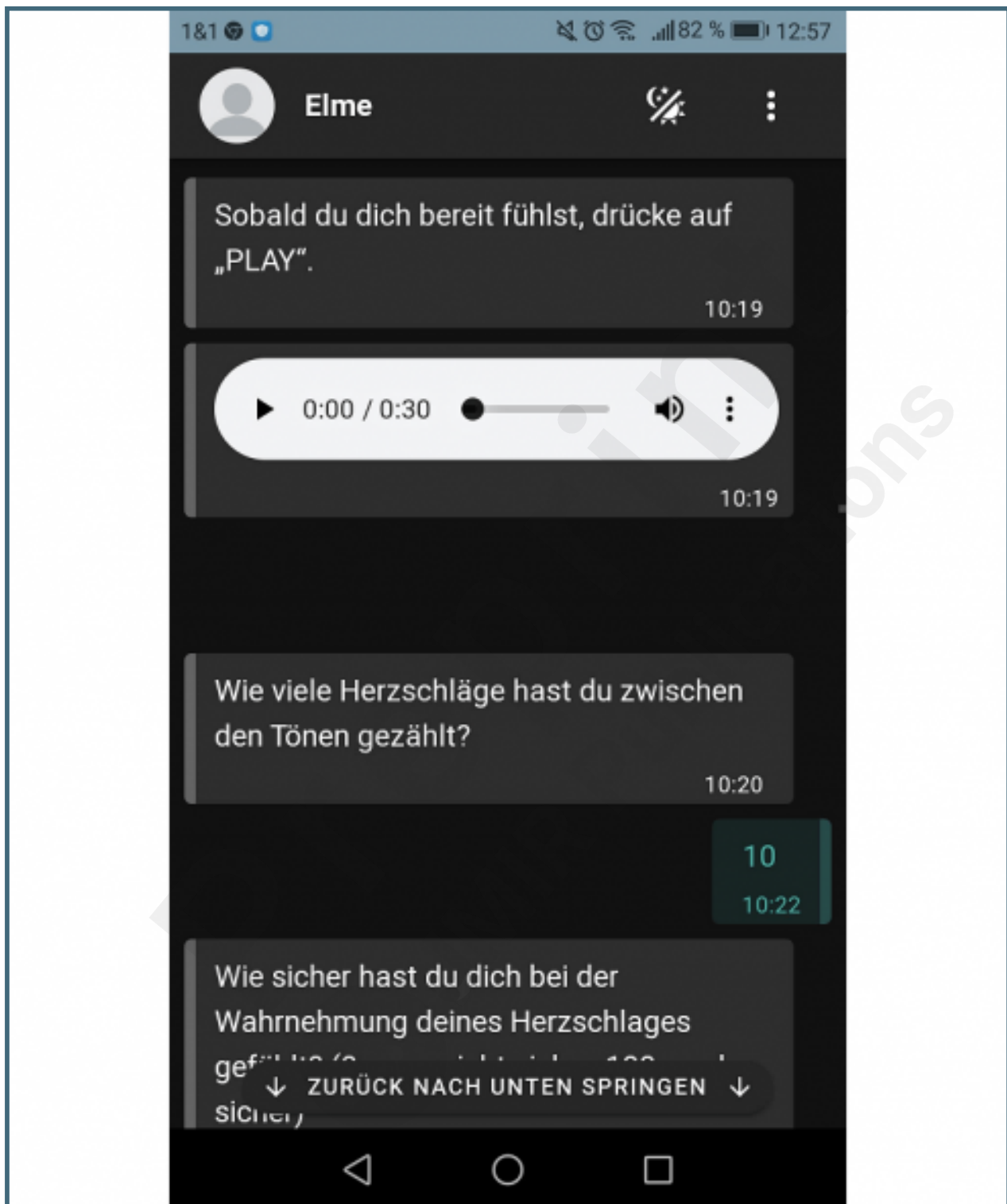
Flow chart of the study procedure.



Sample dialogue of the chatbot interacting with a participant.



Sample dialogue of the chatbot interacting with a participant.



Multimedia Appendixes

Supplementary Material.

URL: <http://asset.jmir.pub/assets/eb5316043ac00a8bc92e481606310de3.docx>

