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Mobile health intervention CanRelax reduces distress in people with cancer in a randomized controlled trial

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Mindfulness and relaxation exercises are effective face-to-face interventions for reducing distress in people with cancer. Their effectiveness in mobile health settings has yet to be investigated. This study evaluated the effectiveness of the CanRelax 2 app in reducing distress in people with cancer. German-speaking adults diagnosed with cancer within the last five years with elevated distress levels (Distress Thermometer ≥5) were recruited. Participants were randomized to the CanRelax 2 app or a waitlist control group. The primary endpoint was the Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS) after 10 weeks (210 participants). We observed a clinically meaningful larger reduction in PHQ-ADS scores in the intervention group compared to the control group (−3.7, 95%-CI from −5.7 to −1.6; $p = 0.0005$). Similar effects were found for distress, well-being, and self-regulation. Our results confirm the effectiveness of a mobile health app in reducing distress in people with cancer. Registration: German Clinical Trials Register (DRKS00027546) on 23.02.2022

Mindfulness and relaxation techniques have demonstrated effectiveness in both face-to-face and web-based settings[1]. Studies have consistently shown that face-to-face mindfulness and relaxation interventions can alleviate distress[2], anxiety[3], depression[4], and improve quality of life[5] across various clinical populations, including those affected by cancer. However, the evidence supporting the effectiveness of mindfulness and relaxation mobile apps in clinical populations remains limited. Most prior research on mindfulness and relaxation apps involved healthy individuals, with many reporting beneficial effects on health surrogates[1,6]. In clinical populations, such apps showed promising benefits for individuals with conditions such as diabetes[7] and depression[8], but their effects on individuals experiencing pain remain inconclusive[9,10]. Thus far, only a limited number of studies have examined the effectiveness of mindfulness and relaxation apps within cancer populations[10–13], and to our knowledge, none of these apps were specifically designed for people with cancer.

Conversational agents, also known as chatbots, are computer programs that offer natural language interactions to humans[14]. People can build a working alliance with conversational agents[15], an important relationship quality robustly linked to treatment outcomes[16]. To this end, conversational agents have been successfully applied in various domains, for example, to support health-promoting lifestyle behaviors[17], disease management[18], or personality development[19]. However, there is limited evidence on the effectiveness of conversational agent-delivered mindfulness interventions[20,21] and, especially, no evidence of improving distress in people with cancer.

Based on promising findings of our feasibility study[12,22], we continued the development of our mindfulness and relaxation app for people with cancer. The new CanRelax 2 app was developed based on a theoretical framework[23]. It includes a diverse array of mindfulness and relaxation exercises, personalized weekly coaching sessions with a conversational agent, and evidence-based behavioral change techniques (BCTs) to encourage participants to engage with a consistent mindfulness and relaxation practice. Supplementary Table 1 in the Supplementary Information provides a comparison of the features included in the first and

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second versions of the app. This study aimed to evaluate the effectiveness of the CanRelax 2 app in reducing distress after 10 weeks in people with cancer compared to a waitlist control group.

Results

Recruitment involved offline and online strategies, with interested individuals self-initiating the download and onboarding. In total, 1.132 individuals downloaded the app, 410 completed the eligibility screening during the onboarding session, and 212 were randomized into the study. Two participants withdrew their consent, resulting in 105 participants in the intervention group and 105 in the waitlist control group (see flow chart in Fig. 1).

Study participants were recruited via direct information provided by physicians (19.5%), flyers (16.2%), personal recommendation (15.2%), electronic newsletters (10.5%), social media (Facebook, 7.6%; LinkedIn, 2.9%), search engines (4.8%), and other channels (23.3%). The majority of the participants lived in Switzerland (84.8%), with a small percentage in Germany (13.8%) and other countries (1.4%). Baseline characteristics of study participants are presented in Table 1.

Effectiveness

For the primary endpoint (PHD-ADS, after 10 weeks) we found a clinically meaningful lower PHQ-ADS in the intervention group (estimated mean 13.5, 95%-CI from 12.1 to 14.9) compared to the control group (17.2, 95%-CI from 15.6 to 18.8) (between group difference −3.7, 95%-CI from −5.7 to −1.6; $p = 0.0005$) (Fig. 2). Additional information about estimated mean scores at baseline is available in Table 2.

Table 2 presents the estimated mean scores at baseline and at week 10 for each treatment condition regarding the secondary outcomes. In addition to reducing distress, the app intervention demonstrated effectiveness in increasing well-being (between group difference 7.5, 95%-CI from 1.5 to 13.6; $p = 0.015$, see also Fig. 3c) and self-regulation (between group difference 0.6, 95%-CI from 0.3 to 0.9; $p < 0.0001$, see also Fig. 3d). Moreover, Fig. 3 also illustrates the treatment effect on biweekly distress measures: the CanRelax 2 app proved efficacious in reducing distress as measured by the PHQ-4 (longitudinal main effect −0.06, 95%-CI from −0.11 to −0.01 and interaction effect of treatment and week −0.08, 95%-CI from −0.15 to −0.01; $p = 0.032$, Fig. 3b). However, we observed only moderate evidence for an effect on distress measured with the Distress Thermometer (longitudinal main effect −0.07, 95%-CI from −0.13 to −0.02 and interaction effect of treatment and week −0.07, 95%-CI from −0.15 to 0.01; $p = 0.077$) (see Fig. 3a).

Sensitivity analyses

In the per-protocol (PP) analysis ($N = 117$; n (app) = 55; n (control) = 62), the finding on the primary endpoint was confirmed with clinically meaningful lower PHQ-ADS scores in the intervention group compared to the control group (−3.1, 95%-CI from −5.3 to −0.8, $p = 0.009$). This corresponds to a standardized effect size of 0.49 (95%-CI from 0.07 to 0.90) which is slightly larger than our assumed effect in the power analysis. Furthermore, in the intention-to-treat (ITT) analysis, the findings concerning the primary endpoint remained robust (−4.0, 95%-CI from −6.1 to −1.9, $p = 0.0003$) even after including well-being, MAIA, Mind Body Medicine practicing scale, ETS, and technology affinity into the model.

Comparison of study completers and study dropouts

Since nearly 50% of the study participants did not complete the post-intervention assessment, we compared the baseline characteristics of study completers and study dropouts (see Supplementary Table 2). There were no

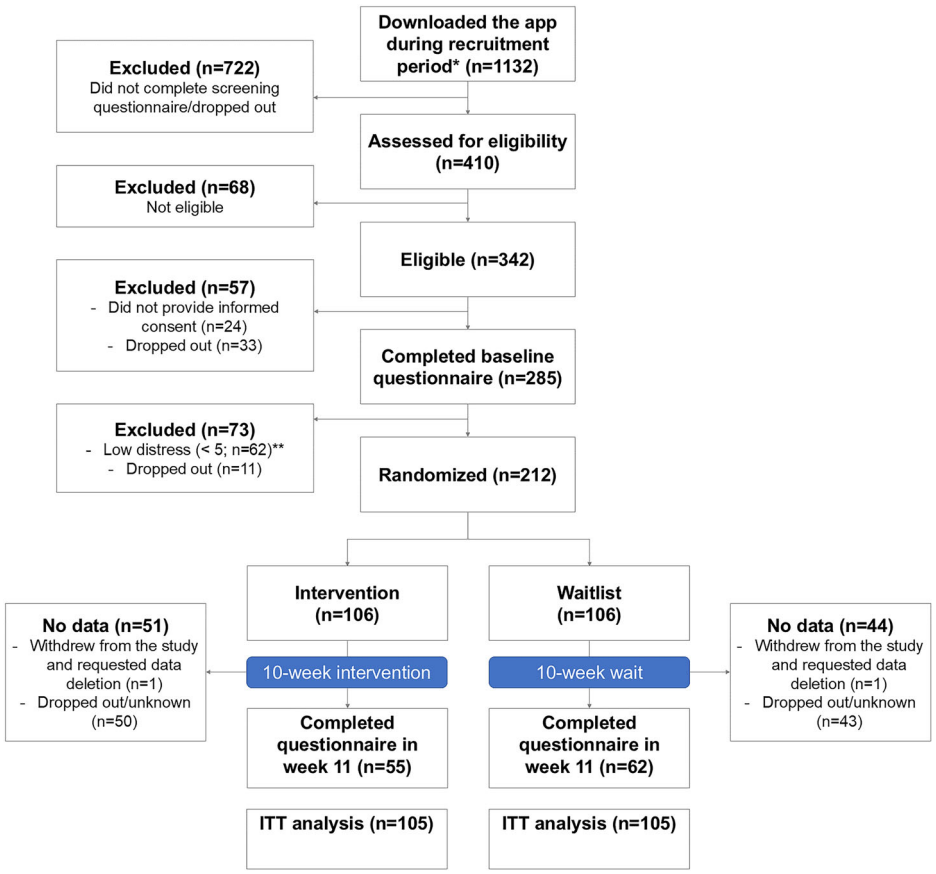

Fig. 1 | Flow chart from download to data analysis. This figure presents a CONSORT diagram detailing the participant flow through the CanRelax trial. It includes numbers from the download, eligibility check, randomization and data analysis. Participants were included from 20.07.2022 to 16.02.2023 (asterisk). People with low distress were excluded from the CanRelax trial but received the app intervention (double asterisk).

meaningful differences between the two groups in sociodemographic variables, clinical characteristics, or health status.

Subgroup analyses

The findings of the subgroup analyses did not indicate any relevant impact of age, previous experience with relaxation exercises, expectations, and affinity to technology (all p values for interaction >0.05). However, we found that female participants benefited substantially from the intervention (estimated mean after 10 weeks PHQ-ADS 13.4, 95%-CI from 11.9 to 14.9) compared to the control group (17.7, 95%-CI from 15.9 to 19.5) (between group difference −4.4, 95%-CI from −6.6 to −2.1; $p = 0.0002$). Conversely, for male participants, there was no difference between the intervention group (estimated mean after 10 weeks PHQ-ADS 13.9, 95%-CI from 10.1 to 17.7) compared to the control group (14.9, 95%-CI from 11.2 to 18.6) (between group difference −1.0, 95%-CI from −6.6 to 4.5; $p = 0.70$) (p value for interaction of PHQ-ADS with sex = 0.17).

Table 1 | Baseline characteristics

	CanRelax 2 app ($n = 105$)	Waitlist control ($n = 105$)
Age (mean, SD)	54.46 (10.76)	54.65 (9.44)
Sex (%) female	86 (81.9)	87 (82.9)
Education (%)		
Primary level	2 (1.9)	2 (1.9)
Secondary level	46 (43.8)	42 (40.1)
Tertiary level	57 (54.2)	61 (58.1)
Working (%)	65 (61.9)	71 (67.6)
Recurrent cancer (%)	32 (30.5)	29 (27.6)
Cancer location (%)		
Breast	43 (41.0)	54 (51.4)
Time since diagnosis in years (mean, SD)	1.79 (2.54)	2.49 (3.25)
Ongoing anti-cancer treatment (%)	31 (29.5)	35 (33.3)
Patient Health Questionnaire Anxiety and Depression Scale PHQ-ADS (mean, SD)	18.29 (6.75)	19.25 (7.25)
Distress Thermometer DT (mean, SD)	6.90 (1.33)	6.95 (1.25)
Multidimensional Assessment of Interoceptive Awareness MAIA, self-regulation (mean, SD)	2.45 (0.94)	2.22 (1.01)
Well-Being Index WHO-5 (mean, SD)	40.65 (18.49)	37.64 (19.97)
Affinity to technology (mean, SD)	9.50 (1.90)	9.87 (1.96)
Expectation for Treatment Scale ETS (mean, SD)	12.50 (3.11)	11.72 (3.01)

DT Distress Thermometer, *ETS* Expectation for Treatment Scale, *MAIA* Multidimensional Assessment of Interoceptive Awareness, *PHQ-ADS* Patient Health Questionnaire Anxiety and Depression Scale (primary endpoint), *SD* Standard deviation, *WHO-5* World Health Organization-Five Well-Being Index.

Safety

In total, 13 serious adverse events (SAEs) were reported, primarily consisting of cancer-related relapses and musculoskeletal issues (including fractures). All SAEs were evaluated as unrelated to the CanRelax 2 app.

Discussion

The CanRelax 2 app was effective in reducing distress in people with cancer after 10 weeks with a moderate treatment effect that is clinically meaningful. Moreover, the CanRelax 2 app improved well-being and self-regulation. These results contribute to a growing body of literature demonstrating the benefits of app-based interventions for people with cancer in addressing distress and other outcomes[24–34].

Possible reasons for the effectiveness of the CanRelax 2 app include its high user engagement, incorporation of relaxation exercises with immediate relaxation effects, the utilization of BCTs, and personalization of the

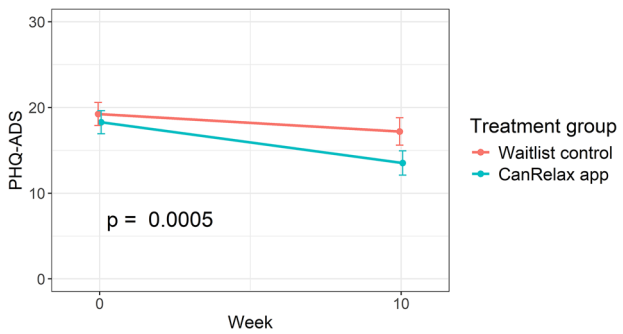

Fig. 2 | CanRelax 2 app group compared with waitlist control (primary endpoint PHQ-ADS) before and after 10 weeks. Main analysis of the primary endpoint PHQ-ADS after 10 weeks. Results are from a linear model (ANCOVA) with treatment as fixed effect and adjusted for sex and baseline distress (PHQ-ADS).

Table 2 | Comparison of intervention and waitlist control in primary and secondary endpoints at baseline, week 10 and between groups at week 10

Outcome variables (estimated means and 95% CI)	CanRelax 2 app ($n = 105$)	Waitlist control ($n = 105$)	Between group difference (95% confidence interval)	p[a]
PHQ-ADS (primary endpoint)				
Baseline	18.3 (16.9–19.6)	19.2 (17.9–20.6)		
10 weeks	13.5 (12.1–14.9)	17.2 (15.6–18.8)	−3.7 (−5.7–−1.6)	$p = 0.0005$
Secondary endpoints				
Well-Being Index WHO-5				
Baseline	40.7 (37.0–44.4)	37.6 (33.9–41.3)		
10 weeks	48.7 (44.3–53.0)	41.1 (37.0–45.3)	7.5 (1.5–13.6)	$p = 0.015$
Self-regulation (MAIA)				
Baseline	2.5 (2.3–2.6)	2.2 (2.0–2.4)		
10 weeks	3.1 (2.9–3.3)	2.5 (2.3–2.7)	0.6 (0.3–0.9)	$p < 0.0001$

CI Confidence interval, *MAIA* Multidimensional Assessment of Interoceptive Awareness, *PHQ-ADS* Patient Health Questionnaire Anxiety and Depression Scale (primary endpoint), *WHO-5* World Health Organization-Five Well-Being Index.

[a]The p value is based on an ANCOVA model with the stratification variable sex and baseline scores as covariates.

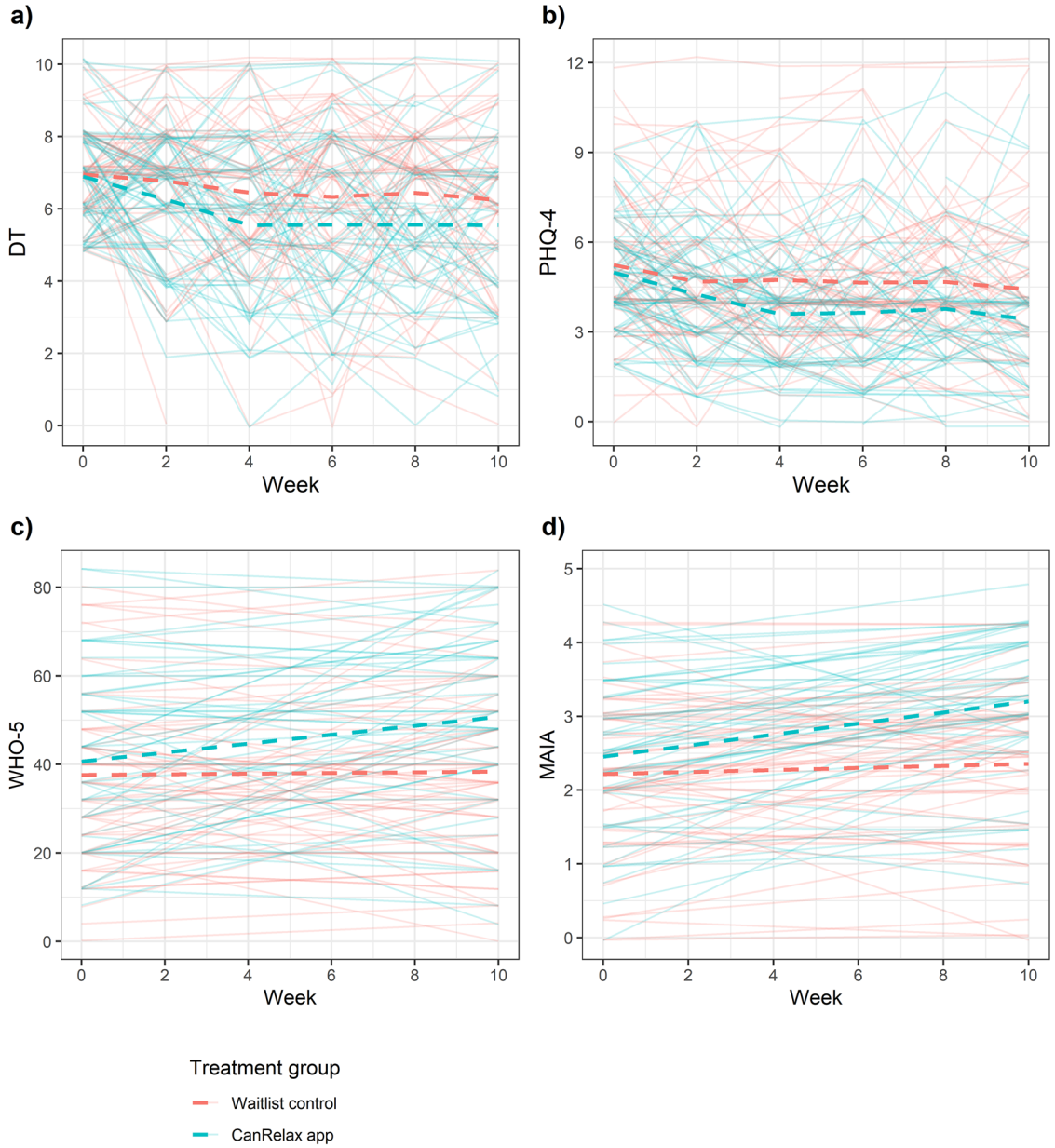

Fig. 3 | Course of secondary outcomes (baseline to week 10). The four Figures show four different outcomes of the CanRelax trial. **a** DT: Distress Thermometer; (**b**) PHQ-4: Patient Health Questionnaire 4; (**c**) WHO-5: World Health Organization-Five Well-Being Index; (**d**) MAIA: Multidimensional Assessment of Interoceptive Awareness (subscale self-regulation). Dashed lines indicate the mean measurements across time points. Results are based on a linear mixed effects model with treatment group (fixed effect), sex (fixed effect), and random intercept and slope for each participant.

intervention. Our exploratory analysis showed that the CanRelax 2 app successfully engaged about two thirds of users over a 10-week period, despite both the app and the study being fully automated[23] and, therefore, lacking the human support commonly provided in similar research (for example[24]). While human support can enhance user engagement[35,36]– an aspect considered crucial for clinical benefits[37,38] – it may limit the scalability and generalizability of study findings to real-world contexts[39]. To engage users while maintaining scalability, we implemented fully automated support strategies in both the app and study processes, including a conversational agent. Another potential pre-requisite for achieving long-term distress reduction are short-term benefits of the relaxation exercises. Our findings from a secondary exploratory analysis suggest that the most frequently utilized relaxation exercises in the CanRelax 2 app positively impact perceived momentary relaxation[40]. These immediate benefits can be considered key working mechanisms that contribute to longer-term outcomes[41]. Moreover, CanRelax 2 included 39 BCTs to support lifestyle changes in participants. BCTs are crucial in influencing user engagement[23] and, potentially, intervention effectiveness. Finally, each participant's journey was highly individualized, which highlights the importance of choice and personalization as potential key ingredients of the intervention. While the combination of mindfulness and relaxation exercises, weekly coaching sessions with a conversational agent, evidence-based BCTs, and a high degree of personalization contributed to the observed distress reduction, the CanRelax 2 app should be regarded as a complex intervention, where no single element is likely to achieve a substantial reduction in distress without the synergistic support of others. Understanding the interplay between these features would require study designs other than an RCT.

Unlike previous studies[24–28], we conducted exploratory analyses specifically to examine sex differences and found that the CanRelax 2 app was particularly effective in reducing distress among female participants. This

finding requires careful interpretation due to the small number of male participants and the exploratory nature of the subgroup analysis. The mean score of distress did not change in the male participants. In contrast, female participants benefited from the app. We recommend that future studies continue with subgroup analyses by sex to explore sex differences in the effectiveness of digital interventions.

The CanRelax 2 app is a scalable, low-risk intervention that requires minimal human resources, making it ideal for large-scale dissemination. Female participants, in particular, benefited from CanRelax, suggesting that women with cancer could be a key target demographic for similar self-care mHealth interventions.

The study has inherent strengths and limitations. Concerning clinical characteristics, we were able to include a broad range of people with cancer, increasing the generalizability of our findings. Further strengths of our study are the use of validated outcome measures and the repeated measurements, which allow a meaningful interpretation of clinical benefits. The additional statistical analyses (PP and comparison of study completers vs. dropouts) confirmed the robustness of the primary analysis, which was important given the dropout rate of 45%. While nearly 50% of participants did not complete the post-intervention assessment at week 10, the observed user engagement and retention rates are still encouraging for a real-world, scalable mobile health intervention that relied solely on internal behavior change strategies rather than external compensation. However, an important limitation is that the validation of the self-reported diagnosis was not possible within our study procedure. Regarding the generalizability of our findings, some limitations must be acknowledged. Our sample primarily included highly educated individuals, more female participants and individuals with breast cancer. Additionally, study participants may have been predisposed to engage with digital technologies like apps. This self-selection could introduce a bias and limit the generalizability of our results.

Our results show that a carefully designed mindfulness and relaxation mobile intervention can benefit people with cancer. Mindfulness and relaxation mobile apps for people with cancer deserve to be evaluated in routine care settings. Future research should explore the reasons for user dropout and identify the specific populations most likely to engage with and benefit from such interventions, to optimize their effectiveness and scalability.

Methods

Study design

We conducted a randomized controlled trial, comparing a mobile health intervention (CanRelax 2 app) to reduce distress in people with cancer (IG) with a waitlist control group (WG). Participants were randomly allocated to one of the two groups in a 1:1 ratio. Waitlist participants gained access to the CanRelax 2 app after 10 weeks.

The trial was conducted in accordance with the Declaration of Helsinki. The trial received ethical clearance from the Ethics Committee of Zurich, Switzerland. We submitted the study synopsis, and after review, the Ethics Committee stated that the study does not fall under the regulation of the Human Research Act of Switzerland (BASEC 2021-01071). The study was registered in the German Clinical Trials Register (DRKS00027546) on 23.02.2022, the first participant was enrolled on 20.07.2022, and the last app session (last visit) took place on 30.09.2023. The study was reported according to CONSORT guidelines (see Supplementary Table 3).

Participants

We opted to include a broad range of participants because distress can affect individuals diagnosed with any type of cancer. Therefore, we enrolled adults (aged ≥18 years) with a cancer diagnosis within the last five years, regardless of type or stage, who scored at least five on the Distress Thermometer[42]. Participants were excluded if they reported suicidal ideation (but they received additional information on how to deal with this situation, i.e., contact with a physician or helpline), had insufficient German-language skills, were pregnant according to self-report (known pregnancy), or mentioned further reasons which would prevent participation in the study (e.g., insufficient knowledge on how to use a smartphone or no regular internet access). Participants were allowed to receive any other kind of co-interventions.

Allocation and blinding

The randomization list with a block length of four was generated by a researcher who was not directly involved in the study. Randomization was stratified based on sex (female vs. male) and was integrated into the CanRelax 2 app. Randomization was done after electronic informed consent in the app. Participants were not blinded for the allocated intervention, but the statistician was initially blinded when performing the analysis.

Interventions

The CanRelax 2 app is a fully automated, theory- and evidence-based relaxation and mindfulness app offering seven audio- or biofeedback-guided mindfulness and relaxation exercises and personalized weekly coaching sessions with a conversational agent integrating 39 BCTs. Screenshots of the app and further details on its theoretic foundation and the development process can be found in prior work[23]. In addition to the main features, the app includes motivating in-app letters from semi-fictional peers, a dashboard summarizing participants' goals and progress, an educational video clip on the mechanisms and benefits of relaxation, FAQ sections offering further information on mindfulness and relaxation exercises and building healthy habits, and tailored reminder notifications. We used an iterative design approach and continuously incorporated user feedback in developing CanRelax 2.

The waitlist control group had access to the CanRelax app solely for completing questionnaires during the 10-week waiting period. They did not have access to any of the app's active components. After the waiting period, they were granted full access to the app.

Procedure

The app was launched in July 2022 through the Apple App Store and Google Play Store (Switzerland, Germany, and Austria). Our study website presented key information (e.g., eligibility criteria, screenshots of the app, and audio samples) and QR codes to download the app. We used social media sites (i.e., Facebook, X, and LinkedIn) and more traditional approaches (e.g., consultations with healthcare providers, printed flyers, newsletters, and a press release by the University Hospital Zurich) to recruit study participants in Switzerland, Germany, and Austria. The last participant was enrolled in February 2023 and completed follow-up in September 2023. The app was free of charge, and participants self-initiated the onboarding process after downloading the app. Users were explicitly informed that they would interact with a conversational agent, not a person. All study processes were fully automated; screening questions, study consent, enrollment, data collection, and all steps up to the completion of follow-up were managed entirely through the app. Participants had no contact with the research team during the study unless participants chose to contact the research team in case of technical issues.

Outcomes

The outcomes were assessed within the CanRelax 2 app in a standardized way. Outcomes were collected at baseline and week 10. Additionally, abbreviated versions of the primary endpoint were administered biweekly throughout the study period. A list of additional baseline measures is described below.

As a primary endpoint, we assessed participants' distress (anxiety and depressive symptoms) at week 10 with the Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS)[43]. This scale comprises the 9-item Patient Health Questionnaire (PHQ-9)[44] and the 7-item Generalized Anxiety Disorder scale (GAD-7)[45]. One item was removed (item 9 of the PHQ-9) since it duplicated an item already included in the screening process. The range of scores was, therefore, from 0 to 48, with a higher score indicating more distress (internal consistency was $\alpha = 0.85$).

As secondary endpoints, participants' distress was recorded every two weeks using the Distress Thermometer (DT)[42] and the PHQ-4[46]. The 1-item DT is a brief screening tool for cancer patients developed by the National Comprehensive Cancer Network (NCCN). Our study utilized it during the screening process to include individuals experiencing at least moderate distress. Additionally, it was employed every two weeks during the intervention phase and at the post-intervention assessment at week 10. The scale ranges from 0 to 10, where 0 indicates low distress, and 10 indicates extreme distress. The PHQ-4 comprises the initial two questions from the depression module (PHQ-2) of the Patient Health Questionnaire (PHQ-D)[47] and the first two questions from the generalized anxiety assessment module (GAD-2)[48] (internal consistency was $\alpha = 0.73$).

Furthermore, we assessed participants' well-being using the WHO-Five Well-Being Index (WHO-5)[49]. The scale ranges from 0 to 100, where a higher score represents better well-being. The internal consistency for this scale was $\alpha = 0.84$ in our study. Participants' self-regulation skills were assessed with four items of the 32-item Multidimensional Assessment of Interoceptive Awareness (MAIA)[50]. The scale ranges from 0 to 5 where a higher score indicates more capacity to regulate distress by focusing on body sensations (internal consistency was $\alpha = 0.85$).

Additional baseline measures

We assessed sociodemographic information and information related to the cancer diagnoses. In addition, we assessed participants' prior expectations regarding the potential benefit of the CanRelax 2 app (Expectation for Treatment Scale (ETS)[51]. The ETS consists of five items and captures expected symptom reduction and increased functioning, coping, and vitality, with higher scores indicating stronger expectations on a scale ranging from 5 to 25 (internal consistency was $\alpha = 0.84$). Technology affinity was assessed using two items adapted from a scale about digital competencies[52] and one item adapted from the affinity for technology interaction scale[53], with higher scores representing higher technology affinity on a scale ranging from 3 to 12 (internal consistency was $\alpha = 0.86$).

Safety and adverse events

Information about serious adverse events (SAE) was collected at 20 weeks and evaluated monthly for relatedness with the study intervention.

Sample size

We assumed a standardized effect size of 0.40 (Cohen's d) for the difference in distress (PHQ-ADS) after 10 weeks between IG and WG, which corresponds to a moderate treatment effect. We aimed to achieve a power of 80% with a two-sided significance level of 5%. Our pilot study showed a pre-post standardized effect size of at least 0.80 in highly distressed patients[12]. If we assume that without any intervention (WG), participants' distress will improve over time (due to factors like regression to the mean or the natural course of their condition), and if the pre-post standardized effect size is 0.40, then the difference in effect magnitude between IG and WG remains a standardized mean difference of 0.40. Based on a power analysis in GPower, for such an analysis, we needed 200 participants in total (100 in IG and 100 in WG). We assumed that approximately 5% of study participants would have insufficient information for a missing data imputation procedure. Therefore, we recruited a total of 210 participants.

Statistical analysis

The primary analysis of the primary endpoint (PHQ-ADS at week 10) was conducted using a linear model (ANCOVA), with treatment (app intervention) versus control (waitlist), adjusted for the stratification variable sex, as well as the baseline distress (PHQ-ADS). The primary analysis was performed in the ITT population. Sensitivity analyses were done in the PP population and with additional covariates in the model (selected according to relevant differences between treatment groups according to the definition of absolute standardized mean difference >0.15 at baseline). Additional analyses for the primary endpoint were conducted in the following subgroups: age (18–44, 45–64, ≥65 years), sex (male vs. female), earlier experience with relaxation and mindfulness-based treatments (no experience vs. with any experience), expectation for treatment scale (3 groups: first quartile, second and third quartile, fourth quartile), and affinity to technology (3 groups: first quartile, second quartile to 7th decile, greater than 7th decile). Missing data were handled using 50-fold multiple imputation (MI) by chained equations (MICE). The MI procedure was performed separately for each treatment group. Results after MI were combined using Rubin's rule.

The analysis of continuous secondary endpoints over time (i.e., distress with PHQ-4 and DT measured biweekly over 10 weeks) were performed using a linear mixed effects model with treatment group (fixed effect), sex (fixed effect), week (fixed effect) as well as an interaction term between treatment group and week, and random intercepts and slopes for each participant. Similar to the analysis of the primary endpoint, for each of the secondary endpoints measured at week 10 (i.e., Well-Being Index (WHO-5) and self-regulation (MAIA subscale)), a linear model (ANCOVA) was fitted. This model included the treatment group, the stratification variable sex, and the respective baseline score of the secondary endpoint as covariates. Again, 50-fold MI was used for these secondary endpoints.

P-values and 95%-confidence intervals are two-sided. The *p*-value of the primary analysis of the primary outcome was considered confirmatory, all other *p*-values were considered exploratory. All analyses were carried out using the statistical software R (version 4.2.2)[54] in combination with dynamic reporting to guarantee reproducibility. The analyses were predefined in a statistical analysis plan (SAP), the SAP document was finalized and signed before data access for analysis.

Data availability

Data are available on OSF: https://osf.io/9nqyb/

Code availability

Code is available on OSF: https://osf.io/9nqyb/

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Author contributions

S.Sc., J.B., C.M.W., M.E., and T.K. conceived the study and methodology. J.B., M.E., and C.W. received funding for this study. S.Sc. developed and implemented the intervention. F.S. and P.S. programmed the CanRelax app under the supervision of T.K. P.H. and U.H. developed the statistical analysis plan (with support from J.B. and S.Sc.) and conducted the statistical analysis. J.B. and S.Sc. wrote the first draft of the manuscript. All authors critically revised the manuscript and approved the final version.

Competing interests

C.M.W. has active research grants to the University for digital health projects from the DIZH, the Swiss Cancer Research foundation, the German health care Innovation Fund, and Newsense Lab GmbH and has received honoraria from Swiss hospitals for scientific presentations on the digitalization and AI in medicine. F.S. is founder of Byldr, which is company for developing mobile health solutions. During the development of CanRelax 2, T.K., F.S., and P.S. were developers and promoters of the open-source software platform MobileCoach. T.K. and P.S. are affiliated with the Centre for Digital Health Interventions (CDHI), a joint initiative of the Institute for Implementation Science in Health Care, University of Zurich, the Department of Management, Technology, and Economics at ETH Zurich, and the Institute of Technology Management and School of Medicine at the University of St.Gallen. C.D.H.I. is funded in part by CSS, a Swiss health insurer, MTIP, a Swiss digital health investor company, and Mavie Next, an Austrian health provider. T.K. was also a co-founder of Pathmate Technologies, a University spin-off company that creates and delivers digital clinical pathways. However, Pathmate Technologies, CSS, MTIP, and Mavie Next were not involved in this research. J.B. received honoraria for workshops on digital health. M.E. received institutional research grants from Kaiku Health and reports grants from Bristol Myers Squibb, Roche and institutional fees as a Scientific Advisory Board Member/Consultant from Roche, outside the submitted work. The remaining authors have no conflicts of interest to declare.

Additional information

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