

Digital stress management in cancer: Testing StressProffen in a 12-month randomized controlled trial

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BACKGROUND: Cognitive-behavioral stress management interventions are associated with improved psychological well-being for cancer survivors. The availability of, access to, and outreach of these in-person interventions are limited, however. The current study, therefore, evaluated the efficacy of StressProffen, a digital application (app)-based stress management intervention for cancer survivors, in a 12-month randomized controlled trial. **METHODS:** Cancer survivors 1 year or less after their treatment (N = 172) were randomized to the StressProffen intervention (n = 84) or a usual-care control group (n = 88). The intervention was delivered in a simple blended care model: 1) 1 in-person introduction session, 2) 10 app-based cognitive-behavioral stress management modules, and 3) 2 follow-up phone calls. Stress (Perceived Stress Scale), anxiety and depression (Hospital Anxiety and Depression Scale), self-regulatory fatigue (Self-Regulatory Fatigue 18), and health-related quality of life (HRQOL; RAND-36) were examined at the baseline and at 6 and 12 months. Generalized linear models for repeated measures were fitted to compare effects over time. **RESULTS:** Participants were mainly female (82%), had a mean age of 52 years (standard deviation, 11.3 years; range, 20-78 years), and had a variety of cancer types (mostly breast cancer [48%]). Over the 12-month study time, the intervention group reported significantly decreased stress ($P < .001$), depression ($P = .003$), and self-regulatory fatigue ($P = .002$) as well as improved HRQOL (for 6 of 8 domains, $P \leq .015$) in comparison with controls. The largest favored effects for the intervention group were observed at 6 months: stress (estimated mean difference [MD], -5.1 ; $P < .001$), anxiety (MD, -1.4 ; $P = .015$), depression (MD, -2.1 ; $P < .001$), self-regulatory fatigue (MD, -4.9 ; $P < .001$), and HRQOL (7 of 8 domains; $P \leq .037$). **CONCLUSIONS:** Digital stress management interventions such as StressProffen have the potential to extend the outreach of psychological interventions and provide easily available and effective psychosocial support for cancer survivors. *Cancer* 2021;0:1-10. © 2021 The Authors. *Cancer* published by Wiley Periodicals LLC on behalf of American Cancer Society This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

KEYWORDS: cancer survivors, cognitive behavioral, electronic health (eHealth), mobile applications, psychological distress, psychoncology, stress management.

INTRODUCTION

Cancer diagnosis and treatment are associated with physical and psychosocial challenges, including discomfort, fatigue, pain, stress, distress, worry, anxiety, and depression.¹⁻³ Quality of life (QOL)¹⁻⁶ and the capacity to control or alter (ie, self-regulate) thoughts, feelings, and behavior^{7,8} are often also affected, and coping during and after cancer can be challenging.^{3,5,8,9}

Psychosocial Interventions for Stress Management and Coping in Cancer

Psychosocial interventions aiming to support stress management and coping have for decades been shown to promote well-being, including improved QOL and reduced stress, distress, anxiety, and depression for cancer survivors.^{2,4,5,10-15} There are also some indications that the positive impact of such interventions may last for more than 10 years.¹⁶

Access barriers to in-person psychological interventions exist, however; they include availability, the geographical distance from the intervention site, costs/limited insurance coverage, and cancer survivors not feeling well enough or comfortable enough to participate in in-person sessions.^{5,15} In light of continued findings that cancer survivors have many unmet needs, including needs for psychosocial support and care,^{5,17} health care delivery methods with higher accessibility and outreach are needed.

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Digital Psychosocial Interventions for Stress Management in Cancer

Digital solutions in the form of electronic health (eHealth) interventions have the potential to enhance the delivery of health care and psychosocial support to cancer survivors. However, published results from randomized controlled trials (RCTs) testing psychosocial eHealth interventions for cancer survivors are mixed and inconclusive.¹⁸⁻²² Examining these findings, researchers have pointed to a need for eHealth interventions for cancer survivors to be theoretically based; to have significant involvement from end users (ie, cancer survivors) and other key stakeholders (eg, health care providers) during the design and development phases; and to include high-quality outcome assessments, larger sample sizes, and longer follow-up periods to establish efficacy.^{19,20,22}

StressProffen: A Digital Stress Management Intervention for Cancer Survivors

In response to identified challenges with eHealth interventions in cancer, the current research team designed and developed StressProffen, an application (app)-based stress management intervention program in support of cancer survivors.^{23,24} StressProffen combines elements from well-known cognitive-behavioral stress management strategies^{4,12,13} and was designed and developed according to user-centered design methods with close collaborations between researchers, cancer survivors, health care providers (eg, psychosocial oncologists), and eHealth experts.²³ In line with recommendations to certify the feasibility of complex medical interventions,²⁵ a feasibility pilot study testing StressProffen revealed positive acceptability, usability, and feasibility, with positive indications related to decreased stress, anxiety, and self-regulatory fatigue as well as improved health-related quality of life (HRQOL) in cancer survivors.²⁴

The initial RCT evaluation of the program (ie, at 3 months) showed significant pre-post between-group differences, with cancer survivors who received StressProffen reporting decreased stress and improved HRQOL in comparison with usual-care controls.²⁶ There was also a decrease in anxiety and depression in favor of the intervention group, although this was not statistically significant. Effect sizes in the 3-month evaluation were generally small, however, with large data variability, which may have contributed to this.²⁶ Also, although a 58% completion rate (ie, at least 7 of 10 modules²⁶) is considered above average for eHealth interventions,²⁷ it is possible that 3 months was not enough time for the participating cancer survivors to

complete the intervention. The current study examined longer term results from the RCT and evaluated the efficacy of the StressProffen intervention program over a 12-month period. It was hypothesized that participants receiving the StressProffen intervention, compared with participants in a usual-care control group, would 6 and 12 months after the intervention initiation experience decreased perceived stress (the primary outcome) and decreased anxiety, depression, and self-regulatory fatigue and improved HRQOL (all secondary outcomes).

MATERIALS AND METHODS

Design and Participants

In this RCT, participants (ie, cancer survivors) were assigned to either 1) the app-based StressProffen stress management intervention or 2) a usual-care control group and were followed for 12 months.

Patients diagnosed with any type or stage of cancer were recruited at a major medical center in Northern Europe or through social media from June 2017 to July 2019. The eligibility criteria were 1) currently or recently receiving cancer treatment (ie, ≤ 1 year after the completion of hospital treatment); 2) being 18 years old or older; 3) being able to speak, read, and understand Norwegian; 4) having access to a smartphone or tablet; and 5) being able and willing to attend 1 in-person introduction session. See also Børøsund and colleagues²⁶ for additional details on the study methodology.

The study was approved by the Regional Committee for Medical and Health Research Ethics (2016/14369) and the Hospital Privacy Protection Committee (2015/10204) and was registered with ClinicalTrials.gov (NCT02939612).

Study Procedure

Patients were informed about the study via medical center social media and/or outpatient clinics/radiotherapy units, and they could request or self-initiate contact with the study team if interested. Participants provided written informed consent and completed baseline study questionnaires/outcome measures before randomization. Computerized randomization allocated study arms on a 1:1 basis (block size, 10) with stratification by gender and diagnosis (ie, breast cancer vs all other cancer diagnoses on the basis of pilot-study findings).²⁴

All outcome measures and program use data were collected electronically through a secure server using an encrypted connection. Participants completed outcome

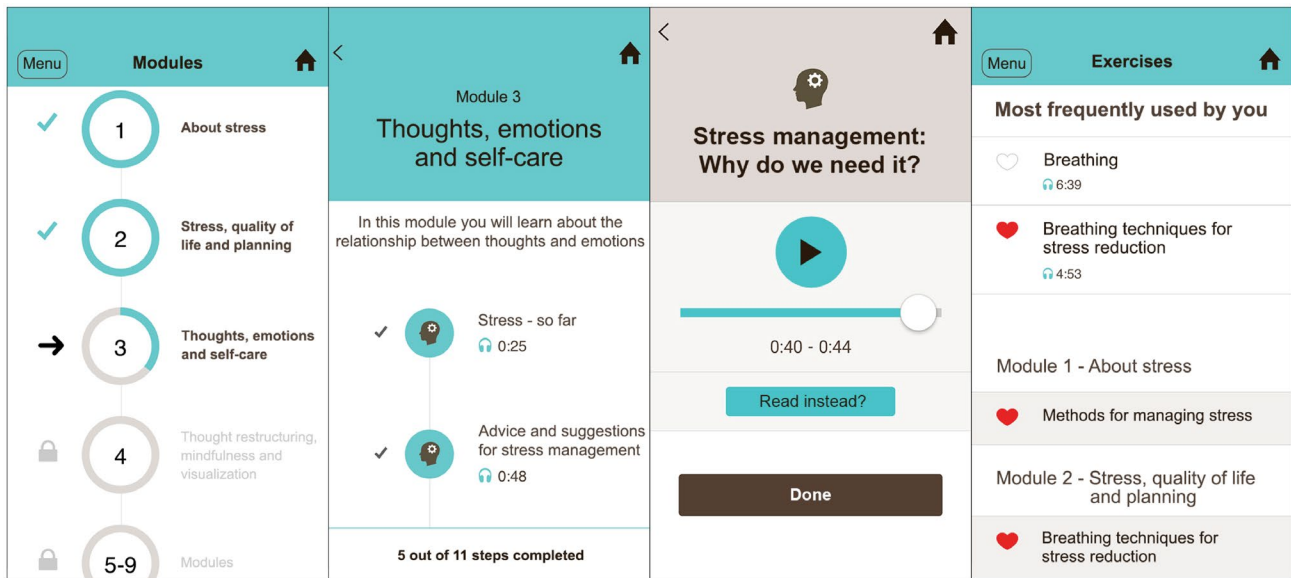


Figure 1. Examples of StressProffen screenshots.

measures at the baseline and at 3 (reported elsewhere),²⁶ 6, and 12 months.

The StressProffen Intervention

In a simple blended care delivery model, the intervention group received the following: 1) an in-person introduction session with study personnel, 2) 10 app-based stress management modules (ie, StressProffen), and 3) follow-up phone calls 2 to 3 and 6 to 7 weeks after the introduction session. The introduction session was structured and served the dual purpose of introducing participants to the stress management concept^{1,10,12} and helping participants to download and get started with the program.

The StressProffen program contains 10 modules with cognitive-behavioral and stress management educational material and exercises: 1) What is Stress; 2) Stress, QOL, and Planning; 3) Thoughts, Feelings, and Self-Care; 4) Mindfulness, Thought Challenging, and Guided Imagery; 5) Stress and Coping; 6) Social Support, Humor, and Meditation; 7) Anger Management and Conflict Style Awareness; 8) Assertiveness and Communication; 9) Health Behaviors and Setting Goals; and 10) Review and Summary.²³ See Figure 1 for examples of program screenshots. For more details about the content, development, and pilot testing of StressProffen, see Børø Sund and colleagues.^{23,24}

Participants were encouraged to complete all 10 modules and to practice the content to become well acquainted with the material. The follow-up phone calls

were conducted by study personnel, structured, and included questions related to program impression and ease of use.

Data Collection and Outcome Measures

A study-specific self-report questionnaire collected demographic, disease, and treatment information at the baseline. Comorbidity was measured at the baseline with the Self-Administered Comorbidity Questionnaire,²⁸ with total scores ranging from 0 to 57 and higher scores indicating a more severe comorbidity profile.

Psychosocial Outcome Measures

Primary outcome

Perceived stress was measured by the Perceived Stress Scale, a 14-item scale measuring feelings and thoughts over the last month.²⁹ Items are rated on a 5-point Likert scale ranging from “never” (0) to “very often” (4). Total scores range from 0 to 56, with higher scores indicating higher perceived stress. Because it is not a diagnostic measure, the Perceived Stress Scale has no cutoff scores (ie, scores are labeled low, moderate, or high).

Secondary outcomes

Anxiety and depression were measured with the Hospital Anxiety and Depression Scale,³⁰ a 14-item measure of anxiety and depression, with 7 items measuring each subscale. Items are rated on a 4-point scale (0-3), with total scores ranging from 0 to 42 and with higher scores

indicating higher anxiety/depression. Score ranges are <8 (nonclinical), 8 to 11 (indicating the presence of anxiety/depression), and >11 (anxiety/depression). Nevertheless, there are some indications suggesting that these cutoff levels are too high for patients with cancer, and this may result in underrecognition of distress.³¹

Self-regulatory fatigue was measured with the Self-Regulatory Fatigue 18 (SRF-18), an 18-item self-report scale gauging the capacity to regulate cognitive, emotional, and behavioral components of self-regulation.³² The SRF-18 contains 8 positively phrased items (eg, “I have no trouble making decisions”) and 10 negatively phrased items (eg, “I experience uncontrollable temper outbursts”). Items are scored on a 5-point Likert scale (1-5), with total scores ranging from 18 to 90 and with higher scores reflecting higher self-regulatory fatigue. The SRF-18 has acceptable internal consistency and reliability.³²

HRQOL was measured with the 36-Item Short Form Health Survey (RAND-36 version),^{33,34} a 36-item measure of physical, role, emotional, cognitive, and social function as well as physical health and general and global health/HRQOL. Subscale scores range from 0 to 100, with lower scores indicating higher disability (0 = maximum disability, 100 = no disability). A mean of 50 is generally considered normative for all subscales. The normative mean for the general Norwegian population may, however, be somewhat higher.³⁵

Program Use

Data related to program use (ie, app progress/activity) were extracted from user logs automatically collected and stored on a secure research server.

Statistical Analyses

Baseline characteristics are summarized as means and standard deviations for normally distributed variables and as medians and ranges for variables with skewed distributions. Categorical data are presented as counts and percentages. For the analysis of between-group differences in outcome measurements, generalized linear models (GLMs) for repeated measures were fitted. To account for statistical dependencies as each individual was measured several times and time spans between the completed measurements varied, an unstructured covariance matrix was used to model variances. Models for each outcome consisted of 3 covariates: measurement (time), group, and interaction term (ie, time and group). All measured time points (ie, for outcome variables) were considered, and the GLM approach was, therefore, adjusted for baseline differences.

Because no statistically significant differences were observed between the intervention group and the usual-care control group in demographic- and disease-related variables at the baseline, no covariates were included in the GLMs. Outcome analyses were conducted with intention-to-treat analyses; all participants in each group were included independently of how much they had used the intervention. Between-group differences were computed as the intervention group change from the baseline to 6 and 12 months minus the control group change from the baseline.

Participants completing at least 70% of the modules (7 of 10) were defined as program completers.^{24,26} Exploratory subanalyses for the intervention group only, using GLMs, were performed to detect potential differences in outcomes between intervention completers and noncompleters.

P values < .05 were considered statistically significant. Statistical analyses were completed with the Statistical Package for the Social Sciences (release 27; SPSS, Inc, Chicago, Illinois) and Stata (version 16).

RESULTS

Sample Description

Among the 175 randomized participants, 3 intervention group assignees were unable to attend the in-person introduction session because of disease progression. The size of the final study sample was, therefore, 172. See Figure 2 for recruitment and retention details. Most participants were recruited by medical center clinic staff (102 of 172; 59%); the remainder were recruited through social media.

The mean age at inclusion was 52 years (standard deviation, 11.3 years; range, 20-78 years). The most common cancer type reported was breast cancer (48%). Most participants were female (82%), were married or cohabitating (70%), reported having a university/college education (81%), and were currently receiving sick leave/disability benefits (70%). See Table 1 for details.

Between-Group Differences

Including measurements from all time points in the model showed statistically significant reductions in perceived stress, depression, and self-regulatory fatigue and improvements in 6 of 8 HRQOL domains over the 12-month study period for the StressProffen intervention group in comparison with the usual-care control group. See Table 2 and Figure 3 for details.

For all outcome measures, the largest intervention effects in favor of the intervention group were observed

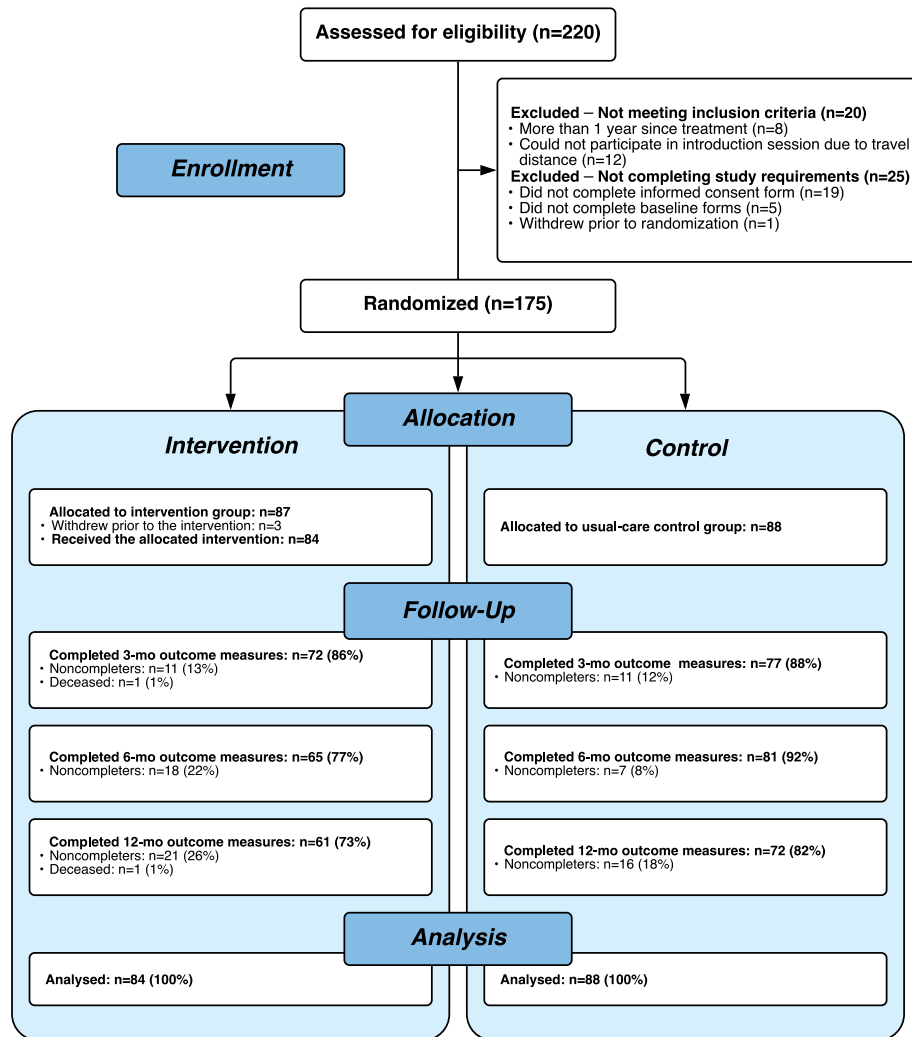


Figure 2. Participant trial flow chart.

at 6 months. Between-group changes from the baseline to 6 months were statistically significant and showed that the intervention group improved on perceived stress, anxiety, depression, self-regulatory fatigue, and 7 of 8 HRQOL domains in comparison with the usual-care control group. See Table 2 for details.

Program Use

Of the 84 participants in the intervention group, 57 (68%) completed at least 7 of the 10 modules within the 12-month study period. Thirty-nine (46%) completed all 10 modules. There were no significant differences in outcomes between intervention completers (ie, ≥ 7 modules) and noncompleters (ie, ≤ 6 modules). Participants used the program a median of 17.5 times (range, 3-170 times), and the median time from first

use to last use was 137 days (range, 10-365 days). At 6 months, 40% (34 of 84) still used the program. This declined to 21% (18 of 84) at 9 months and 12% (10 of 84) at 11 months.

DISCUSSION

The current study was aimed at evaluating the efficacy of StressProffen,^{23,24,26} a digital cognitive-behavioral stress management intervention for cancer survivors. The findings demonstrate a significant positive impact for the intervention group compared with usual-care controls, with between-group differences assessed over 12 months showing significant reductions in perceived stress (ie, the primary outcome) and significant reductions in depression and self-regulatory fatigue and

TABLE 1. Baseline Self-Reported Sociodemographic and Disease-Related Measures (N = 172)

| Characteristic | Intervention Group (n = 84) | Control Group (n = 88) | P |
|---|-----------------------------|------------------------|------|
| Age, mean (SD), y | 51.7 (10.5) | 52.3 (12.0) | .725 |
| Gender, No. (%) | | | .956 |
| Female | 69 (82) | 72 (82) | |
| Male | 15 (18) | 16 (18) | |
| Marital status, No. (%) | | | .387 |
| Married/cohabitating | 56 (67) | 64 (73) | |
| Single/divorced | 28 (33) | 24 (27) | |
| Education, No. (%) | | | .943 |
| Elementary/high school | 17 (20) | 16 (18) | |
| University/college for ≤4 y | 29 (35) | 31 (35) | |
| University/college for >4 y | 38 (45) | 41 (47) | |
| Household annual income, No. (%) ^a | | | .629 |
| <€40,000 | 9 (11) | 9 (10) | |
| >€40,000–€60,000 | 15 (18) | 17 (19) | |
| >€60,000–€80,000 | 5 (6) | 11 (13) | |
| >€80,000–€100,000 | 17 (20) | 14 (16) | |
| >€100,000 | 38 (45) | 37 (42) | |
| Employment status, No. (%) ^b | | | .334 |
| Full-time/part-time work | 18 (21) | 18 (21) | |
| Sick leave/disability benefits | 61 (73) | 59 (67) | |
| Retired/other | 5 (6) | 11 (13) | |
| Treatment, No. (%) ^c | | | |
| Surgery | 66 (79) | 60 (68) | .124 |
| Chemotherapy | 46 (55) | 56 (64) | .236 |
| Hormone therapy | 21 (25) | 23 (26) | .864 |
| Radiation | 34 (41) | 40 (46) | .519 |
| Immune therapy | 8 (10) | 10 (11) | .694 |
| Other | 10 (12) | 14 (16) | .449 |
| Diagnosis, No. (%) ^c | | | |
| Breast cancer | 39 (46) | 44 (50) | .639 |
| Brain cancer | 9 (11) | 4 (5) | .126 |
| Prostate cancer | 6 (7) | 4 (5) | .467 |
| Other | 30 (36) | 36 (41) | .484 |
| Metastases, No. (%) | 12 (14) | 11 (13) | .731 |
| Months since diagnosis, median (range) | 7.0 (0.25–120) | 8.5 (0.25–240) | .183 |
| Comorbidity, median (range) | 3.0 (0–20) | 3.0 (0–17) | .467 |

Abbreviation: SD, standard deviation.

^a€1 is approximately US \$1.2 or approximately 10 Norwegian kroner (spring 2021).

^bPercentages do not add up to 100 because of rounding.

^cParticipants could have received several treatments.

significant improvements in HRQOL (ie, the secondary outcomes).

Psychosocial interventions can support stress management and coping for cancer survivors,^{2,4,5,10–16} but access barriers to such in-person interventions exist.^{5,15} Findings from the use of StressProffen in the current study, therefore, provide great promise for digital solutions as supplements or alternatives to in-person psychosocial health care for cancer survivors. Even though the findings were statistically significant over time, more research is needed to explore the potential reasons why the largest intervention effects appeared around the

6-month follow-up. One explanation could be that psychosocial interventions have the most impact at an early stage in the cancer survivorship journey when the content is still new. If this was the case, however, findings at 3 months²⁶ could have been expected to be the most significant. Because participants were “on their own” progressing in the app (ie, it was user-driven rather than driven by provider guidance), however, it could be that 3 months was not enough time and that the 6-month follow-up revealed the benefits of more thoroughly acquired knowledge, skills, and strategies. A somewhat larger attrition rate in the intervention group compared with the control group from 3 to 6 months could potentially also have played a role if, for example, mainly particularly interested participants remained in the intervention at 6 months. Another factor to consider is that although both groups appeared to improve somewhat from the baseline to 3 months, the intervention group continued to improve, whereas the usual-care control group appeared to experience worsening symptoms from 3 to 6 months. It is possible that cancer survivors in the intervention group did in fact experience a sort of buffering effect from the StressProffen intervention during what may have otherwise been a challenging period in the cancer trajectory for most participants.

The simple blended care delivery model (ie, 1 introduction session, 10 app-based modules, and 2 follow-up phone calls) was used not only to ensure assistance should participants encounter technical issues but also to provide a sense of support throughout the self-management process. Even this simple form of blended care may have had an impact because guided eHealth interventions have been suggested to have better effects than self-guided interventions.²⁰ There was no follow-up contact between the research team and the participants between 6 and 12 months; if the simple blended care delivery induced a sense of guidance, this could have contributed to the more significant findings at 6 months. Another reason could be that the impact decreased as time progressed, and this supports the general notion that most interventions show declining impact over time. It should, however, be noted that even though a clear decline in program use was seen from 6 to 12 months, the impact of the program (ie, acquired knowledge and skills) could still be of benefit independently of actual app use.

Effect sizes in the current study ranged from small (<0.2) to moderate (<0.5). The great variation in data, indicating that some participants may have benefited more from the intervention than others, may have contributed to the limited study effect sizes. However, small

TABLE 2. Effects of StressProffen at 6 and 12 Months: Estimated Means From Generalized Linear Models

| | Intervention Group (n = 84) | | Control Group (n = 88) | | Between-Group Differences ^a | | P | Effect Size β | Time-Trend P ^b |
|----------------------------------|--------------------------------|-----------|---------------------------|-----------|---|--------------|-------|---------------|---------------------------|
| | M | 95% CI | M | 95% CI | MD | 95% CI | | | |
| Perceived stress (PSS-14) | | | | | | | | | <.001 |
| Baseline | 26.7 | 25.0-28.5 | 25.6 | 23.8-27.3 | | | | | |
| 6 mo | 21.1 | 19.2-23.0 | 25.0 | 23.2-26.8 | -5.1 | -7.5 to -2.7 | <.001 | 0.32 | |
| 12 mo | 21.5 | 19.6-23.5 | 22.7 | 20.8-24.5 | -2.3 | -4.8 to 0.1 | .063 | 0.14 | |
| Anxiety (HADS-A) | | | | | | | | | .111 |
| Baseline | 8.5 | 7.6-9.4 | 8.8 | 7.9-9.7 | | | | | |
| 6 mo | 6.6 | 5.6-7.6 | 8.3 | 7.4-9.2 | -1.4 | -2.5 to -0.3 | .015 | 0.19 | |
| 12 mo | 6.3 | 5.3-7.3 | 7.5 | 6.6-8.5 | -1.0 | -2.1 to 0.2 | .101 | 0.14 | |
| Depression (HADS-D) | | | | | | | | | .003 |
| Baseline | 5.4 | 4.6-6.1 | 5.0 | 4.3-5.7 | | | | | |
| 6 mo | 3.5 | 2.7-4.3 | 5.3 | 4.5-6.0 | -2.1 | -3.0 to -1.1 | <.001 | 0.36 | |
| 12 mo | 3.8 | 3.0-4.6 | 4.5 | 3.8-5.3 | -1.1 | -2.0 to -0.1 | .033 | 0.19 | |
| Self-regulatory fatigue (SRF-18) | | | | | | | | | .002 |
| Baseline | 52.0 | 49.7-54.2 | 50.5 | 48.3-52.2 | | | | | |
| 6 mo | 47.0 | 44.6-49.3 | 50.4 | 48.2-52.6 | -4.9 | -7.2 to -2.5 | <.001 | 0.31 | |
| 12 mo | 47.8 | 45.4-50.2 | 48.4 | 46.1-50.6 | -2.0 | -4.5 to 0.4 | .102 | 0.13 | |
| HRQOL (RAND-36) | | | | | | | | | |
| Physical functioning | | | | | | | | | .011 |
| Baseline | 72.9 | 68.4-77.4 | 79.2 | 74.8-83.6 | | | | | |
| 6 mo | 79.4 | 74.5-84.2 | 76.5 | 72.0-81.1 | 9.1 | 2.9 to 15.4 | .004 | 0.22 | |
| 12 mo | 76.2 | 71.2-81.2 | 79.2 | 74.6-84.0 | 3.2 | -0.3 to 9.6 | .335 | 0.06 | |
| Role-physical | | | | | | | | | .001 |
| Baseline | 19.9 | 11.7-28.2 | 37.5 | 29.4-45.6 | | | | | |
| 6 mo | 40.8 | 31.6-49.9 | 33.8 | 25.5-42.2 | 24.5 | 11.4 to 37.6 | <.001 | 0.29 | |
| 12 mo | 34.4 | 25.1-43.8 | 46.3 | 37.6-55.0 | 5.7 | -7.8 to 19.2 | .406 | 0.06 | |
| Bodily pain | | | | | | | | | .004 |
| Baseline | 57.5 | 52.4-62.8 | 64.1 | 59.0-69.3 | | | | | |
| 6 mo | 66.6 | 60.8-72.4 | 59.6 | 54.3-64.9 | 13.6 | 5.8 to 21.4 | .001 | 0.27 | |
| 12 mo | 59.2 | 53.3-65.1 | 64.4 | 58.9-69.9 | 1.4 | -6.6 to 9.4 | .727 | 0.03 | |
| General health | | | | | | | | | .075 |
| Baseline | 50.2 | 45.1-55.2 | 55.6 | 50.6-60.5 | | | | | |
| 6 mo | 52.0 | 46.6-57.3 | 52.1 | 47.0-57.1 | 5.3 | -0.1 to 10.4 | .053 | 0.16 | |
| 12 mo | 49.5 | 44.1-54.9 | 53.9 | 48.8-59.0 | 1.0 | -4.5 to 6.5 | .719 | 0.02 | |
| Vitality | | | | | | | | | .001 |
| Baseline | 38.9 | 34.2-43.6 | 46.5 | 41.9-51.0 | | | | | |
| 6 mo | 50.4 | 45.3-55.4 | 46.9 | 42.2-52.6 | 11.1 | 5.1 to 17.1 | <.001 | 0.28 | |
| 12 mo | 47.4 | 42.2-52.5 | 51.5 | 46.6-56.3 | 3.5 | -2.7 to 9.7 | .268 | 0.09 | |
| Social functioning | | | | | | | | | <.001 |
| Baseline | 51.8 | 46.5-57.1 | 63.1 | 57.9-68.2 | | | | | |
| 6 mo | 68.9 | 63.1-74.6 | 63.0 | 57.7-68.3 | 17.1 | 9.5 to 24.7 | <.001 | 0.34 | |
| 12 mo | 69.9 | 64.0-75.8 | 68.0 | 62.5-73.5 | 13.2 | 5.3 to 21.0 | .001 | 0.26 | |
| Role-emotional | | | | | | | | | .070 |
| Baseline | 46.8 | 37.7-55.9 | 52.7 | 43.7-61.6 | | | | | |
| 6 mo | 64.0 | 53.9-74.2 | 53.7 | 44.5-62.9 | 16.1 | 1.0 to 31.2 | .037 | 0.16 | |
| 12 mo | 66.4 | 56.0-76.8 | 58.3 | 48.6-67.9 | 14.0 | -1.6 to 29.5 | .079 | 0.14 | |
| Mental health | | | | | | | | | .015 |
| Baseline | 65.3 | 61.6-69.0 | 66.5 | 62.9-70.1 | | | | | |
| 6 mo | 74.3 | 70.3-78.3 | 66.7 | 63.0-70.4 | 8.8 | 3.9 to 13.6 | <.001 | 0.28 | |
| 12 mo | 74.9 | 70.8-78.9 | 70.0 | 66.2-73.8 | 6.1 | 1.0 to 11.1 | .018 | 0.19 | |

Abbreviations: CI, confidence interval; HADS-A, Hospital Anxiety and Depression Scale–Anxiety; HADS-D, Hospital Anxiety and Depression Scale–Depression; HRQOL, health-related quality of life; M, estimated mean; MD, estimated mean difference; PSS-14, Perceived Stress Scale; SRF-18, Self-Regulatory Fatigue 18. Three-month findings have been reported elsewhere (see Børøsd et al²⁶).

^aBetween-group differences were computed as the intervention group change from the baseline minus the control group change from the baseline. Negative values for PSS-14, HADS-A, HADS-D, and SRF-18 and positive values for RAND subscales indicate results in favor of the intervention group.

^bInteractions between time and group (eg, a statistically significant P value indicates that the time trajectories were different for the 2 groups).

to moderate statistical effect sizes are not uncommon for psychosocial interventions in cancer and still provide evidence of statistical and clinical significance.^{11,14} The fact that such effect sizes can be achieved with even minimal cost and effort via a digital approach further highlights

the significant potential for the outreach and impact of digital self-management interventions.

In addition to the longstanding limited availability of and access to psychosocial interventions for cancer survivors, a failure to meet the psychosocial needs of cancer

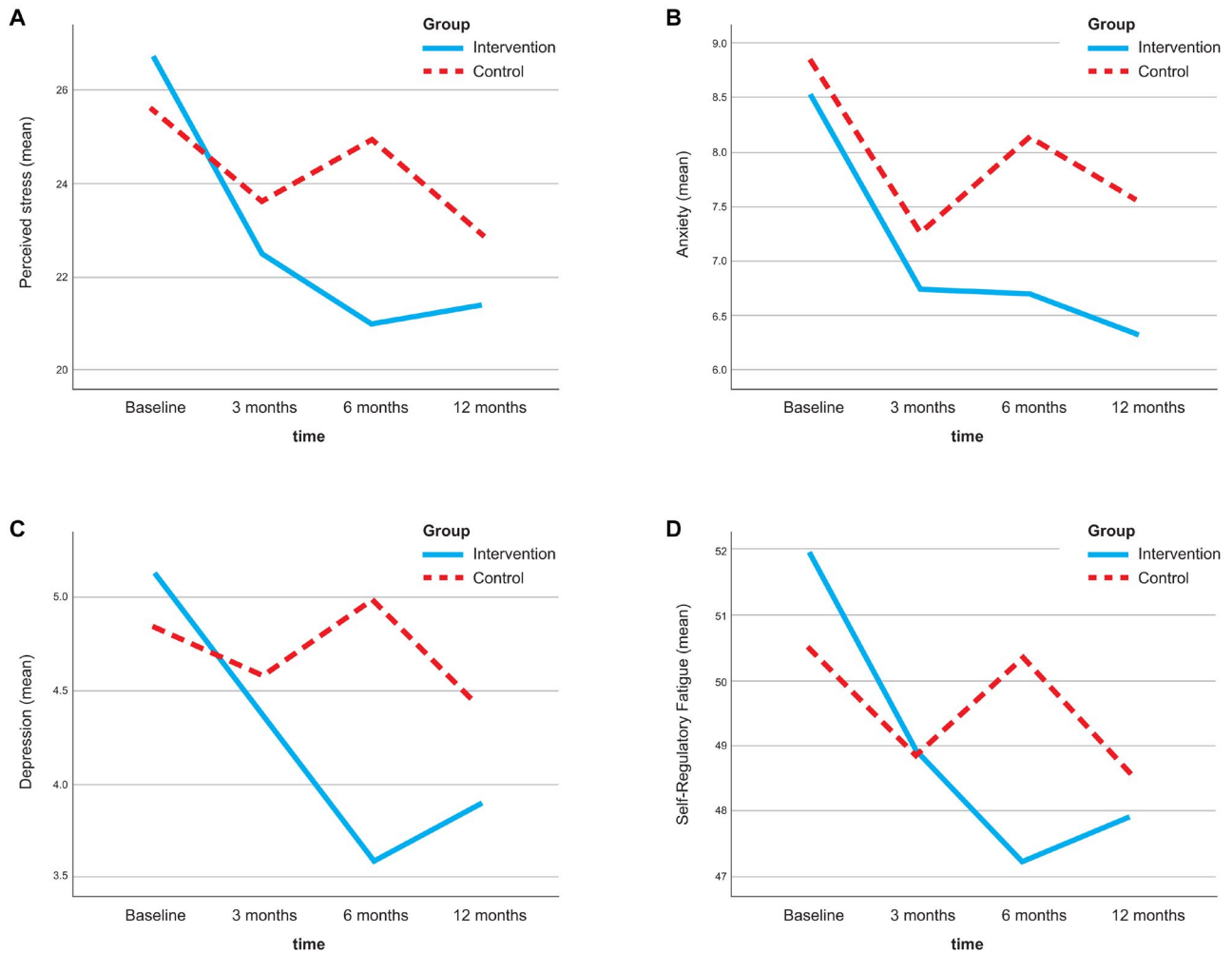


Figure 3. Estimated marginal means of (A) perceived stress (PSS-14), (B) anxiety (HADS-A), (C) depression (HADS-D), and (D) self-regulatory fatigue (SRF-18) for the intervention group ($n = 84$) and the usual-care control group ($n = 88$). Higher scores are indications of higher levels of stress, anxiety, depression, and self-regulatory fatigue. HADS-A indicates Hospital Anxiety and Depression Scale-Anxiety; HADS-D, Hospital Anxiety and Depression Scale-Depression; PSS-14, Perceived Stress Scale; SRF-18, Self-Regulatory Fatigue 18.

survivors during the recent coronavirus disease 2019 pandemic,¹⁷ a pandemic bringing with it an instant need for new ways to deliver care, has also been indicated. Digital stress management solutions such as StressProffen may contribute to solving, or at least limiting, these types of challenges by providing innovative options for the outreach of effective psychosocial interventions even during challenging times.

To achieve the intended impact of interventions, adherence and continued use are vital. With adherence/completion rates for eHealth interventions sometimes as low as 20% to 40% (ie, 60%-80% attrition), however, the potential for intervention evaluation and effect is seriously compromised, and adherence and attrition surface as major

obstacles to the realization of eHealth interventions.^{21,27,36} In the current study, as many as 68% of the participants could be considered completers (ie, completing ≥ 7 of 10 modules within the study period).^{24,26} Completer status did, however, not affect outcomes, and this might indicate that even modest use of the StressProffen program could potentially have a positive impact.

The current study indicates that even minimal blended care models can strengthen delivery and the chance of impact. Future research should explore the extent needed to achieve such an impact. Could 1 phone call, or a simple introduction by a health care provider, be enough? Also, such explorations could determine whether completely user-driven digital self-management programs

can be effective; if so, this could mean even more simple, cost-effective health care. Future studies should also aim to rigorously compare well-established in-person psychosocial interventions for cancer survivors with comparable digital interventions such as StressProffen.

Limitations

This study has several limitations. First, recruitment allowed for cancer survivors to contact the research team if they were interested in participation, and it can be assumed that these participants (41%) were particularly motivated; this potentially affected study generalizability. Second, disease status and treatment status were self-reported and could not be verified. Third, although a wide variety of cancer diagnoses were included in the current study, participants were mainly female, with a majority being breast cancer survivors. To strengthen generalizability and clinical utility, future research should aim to improve the gender balance and include more heterogeneous cancer survivor populations. Fourth, baseline scores were low to moderate for the majority of the outcome measures in the current study. It is possible that enrolling cancer survivors with higher baseline distress levels (ie, minimal distress score inclusion criteria) could have resulted in even higher intervention benefits for the participants. Finally, because of the access/not-access nature of the intervention, group allocation could not be blinded. Intervention group participants may, therefore, have anticipated potential effects, particularly if they were aware of findings from existing StressProffen publications.^{24,26}

In conclusion, in an RCT, cancer survivors receiving StressProffen, a digital cognitive-behavioral stress management intervention delivered in a simple blended care model, compared with usual-care cancer survivor controls, reported improvements in perceived stress, depression, self-regulatory fatigue, and HRQOL over a 12-month time period. Digital stress management interventions such as StressProffen, built on evidence, with significant stakeholder involvement in the design and development process, have the potential to improve outreach and provide easily available and effective psychosocial support for cancer survivors. This type of care model could be especially effective in meeting distress management guidelines and accreditation standards in the provision of comprehensive cancer care.

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CONFLICT OF INTEREST DISCLOSURES

Shawna L. Ehlers reports a role with Ask Mayo Expert. Lise Solberg Nes reports being an unpaid board member for dHealth AS. The other authors made no disclosures.

AUTHOR CONTRIBUTIONS

Elin Børøsd: Conceptualization, methodology, data collection, supervision, and writing (original draft, review, and editing). **Shawna L. Ehlers:** Conceptualization, methodology, and writing (review and editing). **Matthew M. Clark:** Conceptualization, methodology, and writing (review and editing). **Michael A. Andrykowski:** Conceptualization, methodology, and writing (review and editing). **Milada Cvancarova Småstuen:** Methodology and writing (review and editing). **Lise Solberg Nes:** Conceptualization, methodology, supervision, and writing (original draft, review, and editing). All authors gave final approval for the manuscript submission.

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