Impact of a novel nurse-led prechemotherapy education intervention (ChemoEd) on patient distress, symptom burden, and treatment-related information and support needs: results from a randomised, controlled trial

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Background: High levels of distress and need for self-care information by patients commencing chemotherapy suggest that current prechemotherapy education is suboptimal. We conducted a randomised, controlled trial of a prechemotherapy education intervention (ChemoEd) to assess impact on patient distress, treatment-related concerns, and the prevalence and severity of and bother caused by six chemotherapy side-effects.

Patients and methods: One hundred and ninety-two breast, gastrointestinal, and haematologic cancer patients were recruited before the trial closing prematurely (original target 352). ChemoEd patients received a DVD, questionnaire list, self-care information, an education consultation 24 h before first treatment (intervention 1), telephone follow-up 48 h after first treatment (intervention 2), and a face-to-face review immediately before second treatment (intervention 3). Patient outcomes were measured at baseline (T1: pre-education) and immediately preceding treatment cycles 1 (T2) and 3 (T3).

Results: ChemoEd did not significantly reduce patient distress. However, a significant decrease in sensory/psychological (P = 0.027) and procedural (P = 0.03) concerns, as well as prevalence and severity of and bother caused by vomiting (all P = 0.001), were observed at T3. In addition, subgroup analysis of patients with elevated distress at T1 indicated a significant decrease (P = 0.035) at T2 but not at T3 (P = 0.055) in ChemoEd patients.

Conclusions: ChemoEd holds promise to improve patient treatment-related concerns and some physical/psychological outcomes; however, further research is required on more diverse patient populations to ensure generalisability.

Key words: cancer, chemotherapy, distress, patient education, symptom burden

introduction

Patients scheduled to receive cancer chemotherapy often suffer pretreatment psychological distress [1–3]. Many report common physical and psychosocial sequelae (e.g. nausea, fatigue, hair loss, treatment-related worry) cause a great deal of concern [4–6] and rates of psychiatric and psychosocial morbidity are typically high [2, 7, 8]. Patients require detailed preparatory information to cope with chemotherapy treatment and the self-management [9] of often complex treatment-related side-effects in the community. However, current research indicates that patients report high levels of unmet need in relation to the provision of self-care information and the things they can do to keep well [10, 11].

The high incidence of patient psychological distress and need for self-care information suggest that current prechemotherapy preparation is suboptimal; however, few studies have addressed this area. An early study showed that information about side-effects improved patient self-care activity [12]; however, this was a study of only 60 participants, involving relatively simple chemotherapy regimens. Audiovisual resources within chemotherapy education have recently been shown to reduce patient anxiety [13] and promote higher recall of symptom information [14]. A second trial of 70 participants showed a nonstatistically significant increase in self-care behaviours and reduction in reported symptoms following changes to prechemotherapy education; however, interpretation is difficult
given that this study was likely underpowered [15]. All other studies have only focused on improvements in specific side-effects such as oral mucositis [16, 17] or fatigue, as a result of changes to patient education [18]. Thus, the overall evidence base for preparation of patients for chemotherapy is limited.

Literature regarding the preparation of patients for potentially threatening medical procedures [9, 19, 20], as well as health education research [21], provides a robust framework that can be adapted to the prechemotherapy setting. Evidence from other patient settings, predominantly surgery, suggests that the provision of adequate and timely sensory, psychological, and procedural information has broad benefits, including reduced psychological distress [9, 20, 22]. The trial reported here systematically applied this and other relevant literature to the development of a nurse-led education intervention (ChemoEd) for patients commencing their first ever chemotherapy treatment. Evaluation of ChemoEd focussed on common chemotherapy-related concerns including psychological distress, treatment-related information and support needs, and symptom burden. Assessment of symptom burden included measurement of both severity and bother caused by six commonly experienced chemotherapy symptoms (nausea, vomiting, infection, hair loss, mouth/throat problems, and fatigue). Symptoms were chosen following a systematic review of the literature [23], which indicated that they were commonly experienced as a result of chemotherapy, were perceived as distressing, and/or were related to patient safety; and that evidence-based self-care strategies were available for amelioration of the symptoms or the distress caused by the symptom.

Assessment of the success of the ChemoEd intervention was based on two research questions: (i) what was the impact of changes to both the timing and the structure of prechemotherapy education on psychological distress on the first day of treatment and (ii) what was the impact of the total ChemoEd package (including subsequent patient follow-up and coaching) on psychological distress, symptoms, and treatment-related concerns over time? The primary hypothesis of this study was that patients randomised to the ChemoEd intervention would report decreased psychological distress at the time of first treatment (Q1) and over time (Q2) when compared with patients in the usual care (control) group. Additionally, it was hypothesised that the total ChemoEd intervention would result in decreased cancer treatment-related information and support needs and would lead to decreased burden (severity and bother) caused by six common chemotherapy symptoms (nausea, vomiting, infection, mucositis, fatigue, and hair loss).

patients and methods

The study was conducted at the Peter MacCallum Cancer Centre (Peter Mac), a specialist cancer hospital in Melbourne, Australia. The Human Research Ethics Committee at Peter Mac approved the study. The study was registered with the Australian New Zealand Clinical Trials Registry. A consecutive sample of patients attending the outpatient clinics at Peter Mac between September 2005 and December 2007 were screened for eligibility. Eligibility criteria included the following: (i) diagnosis of nonmetastatic breast, gastrointestinal, or haematologic cancer (Hodgkin’s lymphoma, non-Hodgkin’s lymphoma, and chronic lymphocytic leukaemia); (ii) scheduled to receive first ever course of chemotherapy; (iii) planned to receive at least three cycles of chemotherapy given with curative intent; (iv) aged >18 years; and (v) able to speak, read, and write in English. Exclusion criteria included the following: Eastern Cooperative Oncology Group (ECOG) performance status score more than two and severe cognitive/emotional issues as determined by the patient’s treating oncologist. Breast, gastrointestinal, and haematologic cancers were chosen for inclusion in this study due to their high prevalence in the cancer population and to assess the intervention in both solid and non-solid tumour groups.

study design

A parallel group-prospective randomised, controlled trial was undertaken with patients randomised to receive ChemoEd or routine care/prechemotherapy education. Baseline data (T1) were collected in the week preceding patients’ first ever chemotherapy. Randomisation was completed via random number generator with stratification for cancer type and treatment toxicity (high versus low, predetermined by clinical investigators based on the likelihood of patients developing febrile neutropenia during treatment). Individual patients were randomised immediately following completion of baseline measures via sequentially numbered opaque envelopes concealing group allocation. Blinding of participants to group allocation was not possible given the nature of the intervention; however, research assistants not involved in the intervention delivery carried out all patient data collection.

intervention framework (ChemoEd). ChemoEd was informed by evidence relevant to four key domains: preparing patients for potentially threatening procedures [9, 19, 20], tailoring to the specific needs of individuals [21, 24], emphasising evidence-based self-care [23], and psychosocial support [20]. It consisted of four key resources including a chemotherapy educational DVD [25, 26], a DVD question-prompt list to facilitate education tailoring, one-page drug information sheets that contained sensory and procedural information, and one-page evidence-based self-care brochures on 16 different topics outlining strategies to lessen common chemotherapy side-effects. These resources were utilised within a structured delivery framework (Figure 1; supplemental Appendix S1, available at *Annals of Oncology* online). ChemoEd sessions focused on eliciting and responding to patient-identified concerns/fears, delivery of tailored evidence-based messages about chemotherapy side-effects, and discussion and coaching of relevant self-care strategies to manage toxic effects/side-effects and psychological distress. All ChemoEd prechemotherapy education sessions (i.e. intervention 1) were scheduled between 1 and 7 days before first treatment, in a private room away from the treatment area.

routine care/prechemotherapy education. Routine care consisted of a nurse-led education session covering common side-effects of chemotherapy provided on the first day of treatment either in the treatment chair of a shared ward or in the communal waiting area. The educational DVD used in ChemoEd was freely available in the chemotherapy day unit; therefore, use of this resource was monitored. No follow-up patient contacts were scheduled as part of routine care.

outcome measurement

Written informed consent was obtained at T1 before randomisation and before any study procedures. Patients completed self-administered questionnaires in outpatient clinics at T1, T2, and T3.

clinical data. Information on ECOG performance status, cancer type, stage, and treatment regimen was collected from the patient record.

demographic data. Age and gender were collected from the patient record. Other items were collected at T1 in the patient-completed questionnaire (marital status, current employment, education, and country of birth).
psychological distress. Psychological distress was assessed with the Hospital Anxiety and Depression Scale (HADS) [27, 28] at T1, T2, and T3. The HADS is a self-report 14-item measure with two subscales (anxiety and depression), which may be scored by scale or as a total score representing overall distress. The HADS total score provides a robust indicator of psychological morbidity in cancer patients [29–32] and exhibits sound psychometric properties [33–36] including responsiveness to change [13]. A total score of 15 is considered a good predictor of general psychological morbidity/distress [32, 37–39].

common chemotherapy-related symptoms. These were assessed with the Chemotherapy Symptom Assessment Scale (C-SAS) [40] at T1 and T3. This is a 24-item self-report measure with demonstrated validity, reliability, and responsiveness to change in cancer patients [40]. Respondents indicate if they have experienced any of a list of symptoms since their last chemotherapy treatment (0 = no and 1 = yes). If a symptom is marked as present, they then rate the severity of that symptom (1 = mild to 3 = severe) and the extent of bother caused by it (0 = not at all to 3 = very much).

intervention fidelity

Nurses who educated participants with ChemoEd were recruited from the chemotherapy day unit and trained in delivery of the intervention content and in communication skills (responding and eliciting to emotional cues;...
supplemental Appendix S1, available at Annals of Oncology online). Intervention nurses were not permitted to provide education to participants in the routine care group and were discouraged from talking about the intervention with other nurses.

Prechemotherapy education sessions for all study participants were audio taped and content analysis carried out to assess intervention fidelity, consistency over time, and diffusion into routine care. Checklists were completed for each component of the ChemoEd intervention to assess completeness.

**study end points**

The primary end point of this study was psychological distress at T2 and T3 as measured by the HADS. Secondary end points included treatment-related information and support needs (as measured by the CaTS) and decreased symptom burden (severity and bother) due to six common chemotherapy symptoms as measured by the C-SAS (nausea, vomiting, infection, mucositis, fatigue, and hair loss). It was hypothesised that patients receiving the ChemoEd intervention would have significantly lower psychological distress at T2 and T3, treatment-related information/support needs, and symptom burden when compared with patients in the control group.

**statistical power and analyses**

Initial sample size calculations were based on the detection of a small effect [41] on the primary outcome measure of psychological distress as measured by the HADS. To detect an effect size of 0.30 standard deviations (two-sided 5% significance level; 80% power), 352 participants were required.

**statistical analysis**

All data were analysed with SPSS version 17.0 (SPSS, Chicago, IL). Independent samples *t*-tests for continuous variables, Mann–Whitney *U* tests for ordinal variables, and Pearson’s *χ*² or Fisher’s exact test for nominal variables were used to compare demographic, clinical, and psychosocial characteristics of the control and intervention arms at baseline. Questionnaire compliance (missing items and forms) was also assessed. Analyses were carried out using the ‘all-available’ approach to maximise available pairwise information. With this approach, the number of observations used in calculations varies for each analysis [42].

The impact of the first intervention session of ChemoEd on psychological distress on the first day of treatment was assessed using analysis of covariance (ANCOVA). Additionally, the impact of the total ChemoEd intervention on psychological distress and cancer treatment-related concerns was evaluated using ANCOVA [43]. Separate ANCOVAs were run for each outcome variable (HADS total scores and CaTS subscale scores used as dependent variables) at each follow-up assessment with study group as the between-subjects factor and relevant baseline score as the covariate. Initially, age, marital status, sex, functional impairment, and symptom prevalence were included as covariates; however, these made little difference to interpretation, so were excluded. In these analyses, alpha was set at 0.05 (two-tailed).

Odds ratios and Pearson’s *χ*² were used to assess the relationship between the prevalence of common chemotherapy side-effects and study group at T1 and T3. Mann–Whitney *U* tests were used to assess the impact of ChemoEd on the severity of and bother caused by common chemotherapy side-effects. A more stringent alpha of 0.01 (two-tailed) was employed to correct for multiple testing.

Exploratory subgroup analyses were undertaken in those patients with elevated psychological distress (≥15 on HADS) [30, 37, 39] at T1. Independent samples *t*-tests were used to identify group differences in mean distress levels at baseline. Two separate ANCOVAs were subsequently run (for each follow-up assessment)—with study group as the between-subjects factor, T2 and T3 HADS total scale scores used as dependent variables, and baseline/T1 HADS score as the dependent measure.

**results**

**trial profile**

Overall, 2370 outpatients were screened for eligibility (Figure 2) and 309 were eligible. A total of 247 patients (80%) were approached and 192 (82%) patients consented and completed baseline measures (T1) between September 2005 and December 2007.

There were no significant differences in patient characteristics between groups (Table 1).

**prechemotherapy education content and intervention fidelity**

All patients randomised to ChemoEd received the educational DVD after completing the baseline questionnaire and 90% (*n* = 89) watched it. In contrast, only 9% (*n* = 8) of control participants reported watching the DVD. The average time for the completion of prechemotherapy education (intervention 1) was 40.36 min (±15.03) and for routine care education 24.28 min (±10.43). Average time taken to complete interventions 2 and 3 were 9.84 (±4.52) and 15.92 (±7.24) min, respectively.

Fidelity assessment of the recorded intervention sessions will be reported elsewhere but completeness of all intervention elements ranged from 72% to 84%, with no significant degradation of intervention nurse performance over the duration of the study. There was no diffusion into usual care identified during assessment of the audiotapes. Almost all (94%, *n* = 92) patients completing T3 measures received all three intervention components.

**questionnaire compliance**

Compliance with questionnaires was high (≥94%) at all planned assessments (supplemental Appendix S2, available at Annals of Oncology online) with minimal missing items for all scales and subscales (<1.0%).

**psychological distress**

At T1, mean HADS scores did not differ significantly between groups, *t*(189) = 0.72, *P* = 0.47. At T2 (after delivery of the first intervention session) and T3, psychological distress scores improved more on average in the treatment than in the control group; however, these differences were not significant (Table 2).

**cancer treatment-related concerns**

At T1, mean SPC scores did not differ significantly between groups, *t*(190) = −0.59, *P* = 0.56, whereas mean PC scores were significantly higher in the ChemoEd group, *t*(190) = −2.3, *P* = 0.022. Adjusting for differences in T1 scores, subscale scores at T3 indicated a significant improvement in the ChemoEd group on both the SPC (*P* = 0.027) and the PC (*P* = 0.03) subscales (Table 3).

**prevalence and severity of and bother caused by six common chemotherapy side-effects**

At T1, there were no significant between-group differences in terms of prevalence, severity, and bother...
related to individual side-effects. While there were few significant differences at T3, prevalence of vomiting as well as the severity of and bother caused by vomiting were reduced in patients receiving ChemoEd (all $P = 0.001$) (Table 4).

** exploratory subgroup analysis—distress**

Prerandomisation, a total of 54 patients [control, $n = 26$ (28%); intervention, $n = 28$ (29%)] reported elevated distress levels (Table 5). At T1, mean HADS scores for patients with elevated distress were significantly higher in the control group,
After adjusting for T1 scores, a significant decrease in psychological distress at T2 ($P = 0.035$) was observed in ChemoEd participants; however, this between-group difference was not maintained at T3 ($P = 0.055$).

Due to scheduled changes in patient prechemotherapy education as part of usual care (changes to patient education materials and timing of education), in combination with slower-than-anticipated recruitment rates, the trial was closed prematurely to avoid potential confounding of study outcomes. This meant that with a final sample of 192 patients, post hoc power analysis (two-sided 5% significance level; sample size group 1 = 98, sample size group 2 = 94) for a small effect ($d = 0.30$) indicated a 54% probability that statistical significance would be indicated on the primary end point, whereas the corresponding probability for a moderate effect ($d = 0.50$) was 93%.

**sample size and statistical power**

Due to scheduled changes in patient prechemotherapy education as part of usual care (changes to patient education materials and timing of education), in combination with slower-than-anticipated recruitment rates, the trial was closed prematurely to avoid potential confounding of study outcomes. This meant that with a final sample of 192 patients, post hoc power analysis (two-sided 5% significance level; sample size group 1 = 98, sample size group 2 = 94) for a small effect ($d = 0.30$) indicated a 54% probability that statistical significance would be indicated on the primary end point, whereas the corresponding probability for a moderate effect ($d = 0.50$) was 93%.

**discussion**

Patients require preparation before commencing chemotherapy, which is commonly a very stressful time. Educating patients before chemotherapy is generally a role of...
Table 2. Results of ChemoEd trial for psychological distress (HADS)

<table>
<thead>
<tr>
<th>Control (routine care), mean (SD)</th>
<th>Intervention (ChemoEd), mean (SD)</th>
<th>b (95% CI)(^a)</th>
<th>F</th>
<th>P</th>
<th>Partial $\eta^2$</th>
<th>Cohen’s $d$</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1</td>
<td>12.1 (7.0)</td>
<td>11.4 (6.2)</td>
<td>0.51 (−0.53 to 1.6)</td>
<td>0.94</td>
<td>0.33</td>
<td>0.005</td>
</tr>
<tr>
<td>T2</td>
<td>10.9 (6.8)</td>
<td>9.9 (5.8)</td>
<td>1.1 (−0.39 to 2.5)</td>
<td>2.1</td>
<td>0.15</td>
<td>0.011</td>
</tr>
</tbody>
</table>

\(^a\)For each analysis, the regression coefficient $b$ provides an estimate of the difference between the mean change scores of study arms $[44]$. HADS, Hospital Anxiety and Depression Scale; SD, standard deviation; CI, confidence interval.

Table 3. Results of ChemoEd trial for the Cancer Treatment Scale

<table>
<thead>
<tr>
<th>Control (routine care), mean (SD)</th>
<th>Intervention (ChemoEd), mean (SD)</th>
<th>b (95% CI)(^a)</th>
<th>F</th>
<th>P</th>
<th>Partial $\eta^2$</th>
<th>Cohen’s $d$</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPC T1</td>
<td>3.0 (0.98)</td>
<td>3.1 (0.90)</td>
<td>0.26 (0.03–0.49)</td>
<td>5.0</td>
<td>0.027</td>
<td>0.027</td>
</tr>
<tr>
<td>SPC T3</td>
<td>2.3 (0.88)</td>
<td>2.1 (0.82)</td>
<td>0.37 (0.13–0.65)</td>
<td>9.0</td>
<td>0.003</td>
<td>0.048</td>
</tr>
<tr>
<td>PC T1</td>
<td>3.4 (1.1)</td>
<td>3.7 (0.90)</td>
<td></td>
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</tr>
<tr>
<td>PC T3</td>
<td>2.5 (0.95)</td>
<td>2.2 (0.95)</td>
<td></td>
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</tbody>
</table>

\(^a\)For each analysis, the regression coefficient $b$ provides an estimate of the difference between the mean change scores of study arms $[44]$. SPC, sensory–psychological concerns subscale; SD, standard deviation; CI, confidence interval; PC, procedural concerns subscale.

the specialist cancer nurse. There is little evidence to guide the structure and delivery of pretreatment education. ChemoEd was developed using high-level evidence—evidence from systematic literature reviews regarding (i) preparation of patients for potentially threatening medical procedures and (ii) the use of evidence-based self-care messages to ameliorate chemotherapy treatment-related side-effects $[23]$. Delivery of the ChemoEd intervention was generally complete and was consistent across the study time frame, with no diffusion into routine care. Likewise 94% of the ChemoEd participants received all three scheduled intervention sessions. Despite high intervention integrity, the primary hypothesis that patients receiving ChemoEd would report decreased distress was not supported. However, several secondary end points were supported including a reduction in information and support needs regarding preparation for treatment and a reduction in the prevalence and severity of and bother caused by vomiting. Compared with patients in the usual care group, patients with elevated distress at baseline randomised to ChemoEd reported a significant decrease in distress at the T2 time point (before cycle 1). This decrease was not sustained at cycle 3. Overall, our data suggest that ChemoEd might be best utilised when tailored to patient baseline (prechemotherapy education) distress. Patients with low distress may need less intense education, whereas those with high distress may benefit from more intensive preparation and follow-up.

An interesting finding of this study was that despite the availability of the education DVD in routine care, few patients in the routine care arm watched this. This demonstrates that structured approaches, such as the use of intervention checklists, may be useful additions to routine practice to ensure patients access available support materials. Access to appropriate information and support materials (such as DVD and self-care brochures) is likely to help reduce treatment-related information and support needs.

Although this study suggests that the ChemoEd intervention is superior to current routine care, the study has several limitations. First, despite being more than twice as large as any prior evaluation of a nurse-led prechemotherapy education program $[12, 14]$, we cannot rule out the possibility that our findings may have been limited by our sample size and that a larger sample may have allowed us to detect smaller between-group differences on our primary outcome variable. However, analyses for all secondary outcome variables, as well as subgroup analyses, were sufficiently powered and all observed differences corresponded with clinically meaningful changes. Second, the study was undertaken at a single specialist cancer hospital and studied a limited patient population. Whether this approach can be applied successfully to people with other cancer types and those treated at nonspecialist centres requires further exploration. Likewise, the study did not assess all chemotherapy types or those patients who had received previous chemotherapy. It involved few patients receiving concurrent radiotherapy or with advanced cancer. In addition, resources were only available in English and therefore those patients not fluent in English and those likely at increased risk for adverse outcomes $[45, 46]$ and most likely to benefit from the intervention were not included in the study. Further studies are therefore warranted to fully explore the potential benefits of the ChemoEd intervention across a more diverse cancer population and to establish whether some groups are more likely to benefit from these education changes.

A further limitation is that the study had no mechanism for monitoring patient use of recommended self-care information in the home environment. There was no way of identifying the extent to which patients undertook suggested self-care activities. It is also possible that the HADS, used to measure psychological distress, was not the ideal instrument to measure treatment-related distress. The HADS is based on Diagnostic and Statistical Manual of Mental Disorders-IV criteria for...
psychiatric disorder, which may not adequately reflect patient experience before receiving chemotherapy. Although the ChemoEd intervention did appear to positively impact on psychological distress, we suggest that further work be undertaken to fully elucidate the nature and measurement of treatment-related distress in the cancer setting and how such distress changes over the course of treatment.

The shift from inpatient to ambulatory delivery of chemotherapy places a significant burden on patients and their carers to assess and manage treatment toxic effects and side-effects in the home environment. ChemoEd provides an evidence-based approach to patient education that impacted positively on sensory and procedural concerns related to treatment, reduced distress in those who were more distressed before treatment, and reduced the severity of and bother related to vomiting. These benefits need to be offset against the increased time taken to provide this type of education. It was not possible to assess other benefits that may have resulted from the intervention such as improved workflow.

| Table 4. Results of the ChemoEd Trial for six common chemotherapy side-effects (C-SAS) |
|---------------------------------------------|---------------------------------------------|---------------------------------------------|---------------------------------------------|
|                             | Control (routine care) | Intervention (ChemoEd) | OR (CI) | P |
|                             | Valid data (n) | % with side-effect | Valid data (n) | % with side-effect | |
| Nausea                       | T1 92 | 23 | 98 | 20 | 0.87 (0.43–1.7) | 0.69 |
|                             | T3 89 | 64 | 94 | 63 | 0.95 (0.52–1.7) | 0.86 |
| Vomiting                     | T1 92 | 5 | 98 | 9 | 1.8 (0.57–5.5) | 0.32 |
|                             | T3 87 | 28 | 93 | 9 | 0.25 (0.10–0.59) | 0.001 |
| Infection                    | T1 94 | 17 | 98 | 13 | 0.75 (0.34–1.6) | 0.47 |
|                             | T3 88 | 27 | 94 | 28 | 1.0 (0.53–2.0) | 0.95 |
| Hair loss                    | T1 94 | 1 | 98 | 1 | 0.96 (0.059–15.6) | 0.98 |
|                             | T3 87 | 76 | 94 | 67 | 0.65 (0.34–1.2) | 0.19 |
| Mouth or throat problems     | T1 93 | 15 | 98 | 10 | 0.64 (0.27–1.5) | 0.31 |
|                             | T3 88 | 53 | 94 | 42 | 0.62 (0.34–1.1) | 0.11 |
| Fatigue                      | T1 94 | 39 | 98 | 51 | 1.6 (0.91–2.8) | 0.11 |
|                             | T3 89 | 81 | 94 | 75 | 0.69 (0.34–1.4) | 0.30 |
| Severity                     | Control (routine care), Mean rank | Intervention (ChemoEd), Mean rank | Mann–Whitney U | P |
| Nausea                       | T1 97.3 | 93.8 | 4341.5 | 0.54 |
|                             | T3 94.7 | 89.5 | 3945.0 | 0.48 |
| Vomiting                     | T1 94.2 | 96.7 | 4387.0 | 0.49 |
|                             | T3 99.3 | 82.3 | 3278.0 | 0.001 |
| Infection                    | T1 99.0 | 94.1 | 4371.0 | 0.34 |
|                             | T3 92.4 | 90.7 | 4057.0 | 0.77 |
| Hair loss                    | T1 96.5 | 96.5 | 4604.5 | 0.98 |
|                             | T3 95.5 | 86.9 | 3699.0 | 0.25 |
| Mouth or throat problem      | T1 99.4 | 92.8 | 4245.5 | 0.17 |
|                             | T3 98.6 | 84.8 | 3508.0 | 0.052 |
| Fatigue                      | T1 90.7 | 102.0 | 4064.0 | 0.11 |
|                             | T3 94.1 | 90.0 | 3995.5 | 0.58 |
| Bothers                      | Control (routine care), Mean rank | Intervention (ChemoEd), Mean rank | Mann–Whitney U | P |
| Nausea                       | T1 97.8 | 93.3 | 4295.0 | 0.45 |
|                             | T3 93.4 | 90.7 | 4061.0 | 0.72 |
| Vomiting                     | T1 95.7 | 95.4 | 4493.0 | 0.92 |
|                             | T3 98.9 | 82.6 | 3313.0 | 0.001 |
| Infection                    | T1 99.4 | 93.7 | 4332.5 | 0.30 |
|                             | T3 92.8 | 90.3 | 4025.5 | 0.69 |
| Hair loss                    | T1 96.5 | 96.5 | 4603.5 | 0.97 |
|                             | T3 98.4 | 84.2 | 3445.5 | 0.059 |
| Mouth or throat problem      | T1 99.4 | 92.8 | 4240.5 | 0.18 |
|                             | T3 97.3 | 86.1 | 3629.0 | 0.12 |
| Fatigue                      | T1 92.6 | 100.3 | 4236.0 | 0.28 |
|                             | T3 90.9 | 93.0 | 4088.5 | 0.78 |

In the case of the C-SAS, some patients did not provide responses to all six items relevant to the six common side-effects. C-SAS, Chemotherapy Symptom Assessment Scale; OR, odds ratio; CI, confidence interval.
Table 5. Results of the ChemoEd trial for patients identified as psychologically distressed* at baseline/T1 (post hoc planned subgroup analysis)

<table>
<thead>
<tr>
<th></th>
<th>Control (routine care), mean (SD)</th>
<th>Intervention (ChemoEd), mean (SD)</th>
<th>b (95% CI)b</th>
<th>F</th>
<th>P</th>
<th>Partial η²</th>
<th>Cohen’s d</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1</td>
<td>21.5 (4.2)</td>
<td>18.9 (4.7)</td>
<td>2.5 (0.19 to 4.9)</td>
<td>4.7</td>
<td>0.035</td>
<td>0.092</td>
<td>0.98</td>
</tr>
<tr>
<td>T2</td>
<td>19.6 (4.1)</td>
<td>15.8 (4.9)</td>
<td>3.6 (−0.082 to 7.3)</td>
<td>3.9</td>
<td>0.055</td>
<td>0.076</td>
<td>0.77</td>
</tr>
<tr>
<td>T3</td>
<td>17.7 (7.3)</td>
<td>13.0 (5.5)</td>
<td></td>
<td></td>
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<td></td>
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</table>

*HADS distress score ≥15.

bFor each analysis, the regression coefficient b provides an estimate of the difference between the mean change scores of study arms [44].

HADS, Hospital Anxiety and Depression Scale; SD, standard deviation; CI, confidence interval.

conclusions

The current ChemoEd program addresses the need for enhanced patient education and preparation for self-management in the ambulatory setting and is potentially suitable as a widespread program to improve patient care. However, its generalisability across different settings and diverse patient populations needs further investigation, alongside consideration of practical aspects such as the cost of additional nursing time and strategies to increase the impact of such interventions on patient outcomes.

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disclosure

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references