Appendix: Amendments to the study protocol

These three amendments were submitted after the original protocol had been approved, and were approved by the Swedish Ethical Review Authority on November 5th 2023, October 19th 2024, and February 19th 2025.

Internet-Delivered Psychological Treatment for Cancer Survivors (IN-FACT-1)

ClinicalTrials.gov identifier: NCT06046586

Amendment #1, approved by the Swedish Ethical Review Authority on November 5th 2023 (identifier: 2023-06373-02)

Broadening of inclusion criterion for psychiatric symptoms

[…] we hereby wish to broaden the inclusion criterion so that we also include applicants who score at least 16 points on the 9-item Fear of Cancer Recurrence Inventory (FCRI-9). This is an established cut-off that is recommended in the literature. As part of this, the FCRI-9 questionnaire is also added as part of the screening battery (previously only at later measurement points). This change applies to both the pilot study and the main trial.

Amendment #2, approved by the Swedish Ethical Review Authority on October 19th 2024 (identifier: 2024-06616-02), on the condition that the information for the study participants specifies that information about healthy lifestyle behaviors is collected

1. New participating research institution

Region Stockholm is added as a participating research institution.

2. Procedural changes based on experiences from the pilot study:

2a. During the main trial, the support program is provided with somewhat less therapist support. Instead of the support person giving feedback every week, feedback will be provided upon request. *[After further discussion, this change was reverted which was considered a minor change without need for further amendments as this was approved previously.]*

2b. During the main trial, all weekly process measures will be administered to all arms.

2c. For the main trial, the following measures are not used: HADS, SF-36. The following are added instead: Health Anxiety Behavior Inventory (HABI; before, weekly, after), Lifestyle behaviors (before, after). (10.1017/S1352465824000377, 10.1017/S146342362300049X)

2d. During the main trial, screening data from all who apply for the project will be used to enable analyses of measurement instrument properties. Recruitment continues as previously intended until 400 participants have been included in the main trial. The following are also administered at screening: HAI-14, SSS-8, and BADS-AC-3.

Amendment #3, approved by the Swedish Ethical Review Authority on February 18th 2025 (identifier: 2025-00851-02)

The primary inclusion criterion (a) is revised. Previously the criterion read: “Cancer survivors 0.5–20 years after primary treatment”, but now the upper time limit is removed. The revised criterion reads: “Cancer survivors at least 0.5 years after primary treatment.”

The second change is a clarification of exclusion criterion (h) “Serious medical diagnosis…”. Cancer survivors who have been treated for hematological malignancies (lymphomas, leukemias, or myeloma) or brain tumors are excluded.

The third change is that the end date of the trial is postponed by one year, because the start now takes place in 2025 (not 2024).