

# A Randomized Controlled Trial on the Efficacy and Safety of the Untire App for Moderate-to-Severe Cancer-Related Fatigue in German Patients

S. Spahrkäs<sup>1</sup>, F. Akbari<sup>1</sup>, K. Abrahams<sup>2</sup>, H.P. Zenner<sup>3</sup>, H. Reitsma<sup>2</sup>, B. Kuiper<sup>1</sup>, E. Schuit<sup>2</sup>

<sup>1</sup>= Full employment at Tired of Cancer B.V.; <sup>2</sup>= Full or parttime employment at THINC, University Medical Center Utrecht; <sup>3</sup>= Full or part-time Employment at CRO Zenner

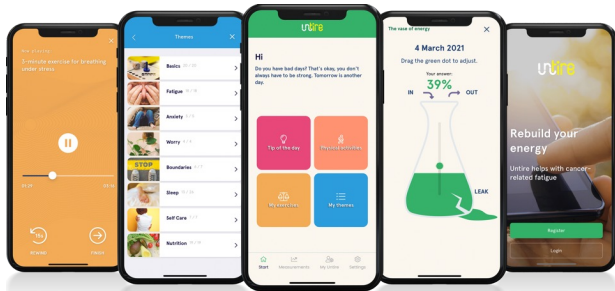


Figure 1. Untire DTx is based on the NCCN guidelines for CRF

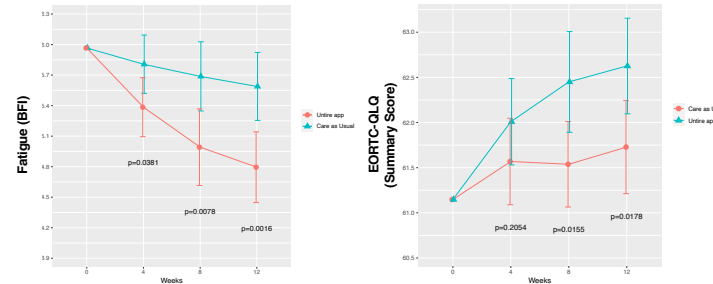


Figure 2. Treatment effects for fatigue and QoL over 12-weeks.

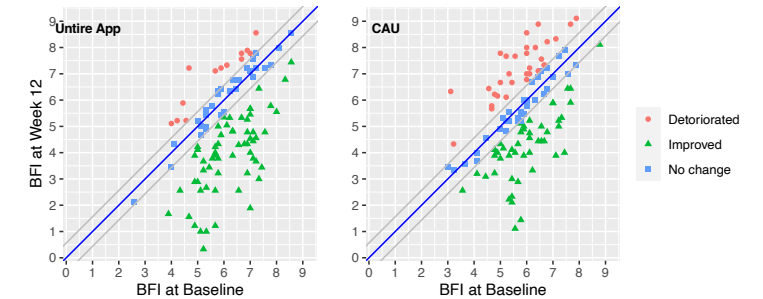


Figure 3. Responder-analysis for fatigue

## Background

- Psycho-oncological services for cancer-related fatigue (CRF) are limited.
- Digital therapeutics (DTx) can bridge this gap.
- This RCT (Untire-II) assessed the German Untire app DTx for patients with moderate-to-severe CRF.
- Hypothesis: Adding the app to Care-as-usual (CAU) improves outcomes of CRF and QoL over 12 weeks as compared to CAU.

## Methods

- 216 patients with moderate-to-severe CRF.
- Randomized 1:1 into control (CAU) (n=111) and intervention (Untire+CAU) (n=104) groups.
- Primary outcome: fatigue; Secondary outcomes: QoL, distress, depression, & anxiety.
- Assessments at 0, 4, 8, and 12 weeks.
- Analyzed with LMM ANCOVAs.
- TT applied, adjusting for baseline values.

## Results

- The intervention group had significantly reduced fatigue at week 12.
- Average fatigue score: Intervention 4.8 vs. Control 5.6 ( $p=0.0016$ ). Effect size ( $d$ ) was 0.5, with a 95% CI of -1.29 to -0.30. The difference of -0.79 was statistically and clinically significant, exceeding the MCID of -0.57. About 60% of intervention group patients improved by more than 0.57 points.
- QoL was significantly higher in the intervention group at week 12 ( $p=0.0178$ ). Effect size ( $d$ ) was 0.4, with a 95% CI of 0.16 to 1.64.
- Sensitivity analyses (per-protocol and reference-based) confirmed the robustness of findings.

## Conclusions

This RCT shows that the **Untire App (DiGA)** is effective and safe for managing CRF, with robust clinical benefits for both moderate and severe fatigue in cancer patients and survivors.

