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POSTER ABSTRACTS

613.ACUTE MYELOID LEUKEMIAS: CLINICAL AND EPIDEMIOLOGICAL

Canadian Cancer Trials Group SC.26 - Emotion and Symptom-Focused Engagement (EASE): A Multi-Site Randomized Controlled Trial of an Intervention for Individuals with Acute Leukemia

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Background: Despite the rapid onset and life-threatening nature of acute leukemia (AL) and its treatment, there is a lack of research on its psychological and physical consequences and even less on interventions to alleviate them *[Bryant 2016]*. A longitudinal study of individuals with newly diagnosed or recently relapsed AL showed substantial physical and psychological distress in this population *[Rodin 2013; Zimmermann 2013]*. Based on these findings, an integrated psychosocial and early palliative care intervention, **E**motion **A**nd **S**ymptom-focused **E**ngagement (EASE), was developed for patients with AL *[Rodin 2015]*. A phase II randomized pilot trial of EASE vs. usual care demonstrated feasibility and showed promising positive effects on traumatic stress symptoms (primary outcome) and other secondary outcomes, including depressive symptoms, number and severity of physical symptoms and related distress, pain, quality of life (QOL), satisfaction with care, and attachment security *[Rodin 2020]*.
*Study design and methods:*The Canadian Cancer Trials Group SC.26 (NCT04224974) randomized phase III trial is underway to test the effectiveness and cost-effectiveness of the EASE intervention in AL. EASE is a novel manualized intervention that combines psychological support with routine symptom screening plus triggered referral to palliative care for symptom control. The goal is to reduce psychological distress and symptom burden, and enhance QOL and satisfaction with care in individuals with newly diagnosed AL undergoing induction therapy.
Participants are randomized in a 1:1 unblinded ratio to usual care (UC) or UC and EASE (EASE). EASE consists of two components: the psychotherapy intervention (EASE-psy) and triggered early palliative care (EASE-phys). EASE-psy involves tailored supportive psychotherapy delivered by trained therapists over the initial 8 weeks following hospital admission for treatment of AL. It combines elements of relational support, affect regulation, and trauma-informed cognitive behavioural therapy. All patients randomized to EASE receive weekly symptom screening during the initial inpatient treatment period with triggered referral to early palliative care (EASE-phys).
Subjects are stratified by centre, age (≤60 vs. >60) and type of acute leukemia (acute myeloid leukemia vs. acute lymphoblastic leukemia). For patients diagnosed with a mixed phenotype acute leukemia, the dominant sub-type is used for stratification

purposes. Patients are ≥18 years, newly diagnosed and recruited within 2 weeks of hospital admission, and receiving or expected to receive induction therapy with curative intent. Current exclusion criteria include major communication difficulties at the time of recruitment; receipt of on-site psychological/psychiatric counselling or palliative care services at the time of recruitment; a diagnosis of acute promyelocytic leukemia or acute leukemia of ambiguous lineage.
The two primary outcomes reflect the dual nature of the physical and psychosocial components of the EASE intervention: Mean severity of traumatic stress symptoms at 4 weeks using the 30-item Stanford Acute Stress Reaction Questionnaire (SASRQ) *[Cardeña 1996]* updated to be DSM-5-concordant *[American Psychiatric Association 2013]* and mean physical symptom severity at 4 weeks using the Memorial Symptom Assessment Scale (MSAS) *[Portenoy 1994]*. Hypotheses will be tested using multilevel modeling with maximum likelihood estimation, conducted as intention-to-treat analyses. Economic analysis will be conducted to measure the cost-effectiveness of the EASE intervention. Utilities will be derived from the EQ-5D-5L *[Herdman 2011]* and FACIT-Sp *[Webster 2003]* questionnaires. The planned sample size of this study is 266. Since January 2022, 53 patients at 4 Canadian centres have undergone randomization.
Conclusion: The information obtained from this study will inform clinicians and decision makers of the value of implementing the EASE intervention in adults with AL.

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