# Maitake for Integrative Cancer Care: An Uncontrolled Trial in People on Systemic Cancer Therapy

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## BACKGROUND & SIGNIFICANCE

Systemic cancer therapies cause neutropenia in up to 50% of patients. While prophylactic G-CSF is often recommended for patients with increased risk of febrile neutropenia, usual management often involves dose reductions, delays, or discontinuation of treatment, which may reduce efficacy. Interventions that improve or stabilize neutrophil counts before dose reductions and/or delays could improve patient outcomes. Maitake is a mushroom that has demonstrated immunomodulatory effects in both murine and human studies, including improved neutrophil functioning in vitro. We evaluated the impact of maitake on immune function in people with cancer undergoing systemic therapy in a prospective, uncontrolled clinical trial.

## STUDY METHODS

**Design**: Patients with cancer receiving systemic cancer treatment were enrolled after treatment began and received 10 mL (400mg) Black Maitake Prothera daily for 12 weeks. Outcomes were assessed at 4, 8, and 12 weeks.

**Setting**: The Centre for Health Innovation (Ottawa) & CCNM Integrative Cancer Centre (Toronto)

**Inclusion Criteria**

- Adults ≥18 years of age diagnosed with cancer and undergoing systemic treatment with chemotherapy or CDK4/6 inhibitors
- At least 8 weeks remaining in cancer treatment regimen

**Exclusion Criteria**

- Hematologic cancers
- Taken mushroom supplements in past 2 weeks
- Diagnosed with diabetes
- Taking hypoglycemic medications, warfarin, or immune checkpoint inhibitors

**Outcomes**

(1) Immune function (absolute neutrophil count) – **Primary outcome**
(2) Immune function (lymphocytes, platelets, neutrophil to lymphocyte ratio, platelet to lymphocyte ratio)
(3) Inflammation (CRP)
(4) Glucose management (HbA1c)
(5) Quality of life (EORTC QLQ-C30)
(6) Safety (adverse event collection)

**Analysis:** Paired t-tests were used to analyze within-person changes in outcomes.

## RESULTS

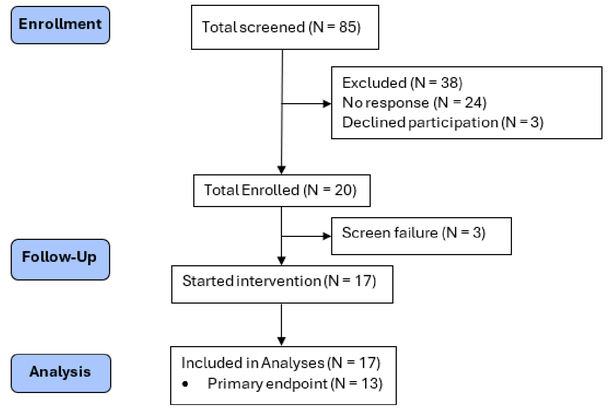



**Figure 1: Participant Flow Diagram.**

| Characteristic | N (%) |
|---|---|
| *Sex* | |
| Female | 15 (88) |
| Male | 2 (12) |
| *Cancer Type* | |
| Breast | 9 (53) |
| Colorectal | 2 (12) |
| Ovary | 2 (12) |
| Lung | 1 (6) |
| Pancreas | 1 (6) |
| Brain | 1 (6) |
| Cholangiocarcinoma | 1 (6) |
| *Cancer stage* | |
| I/II | 3 (18) |
| III/IV | 14 (82) |
| *Treatment Type* | |
| Chemotherapy | 9 (53) |
| CDK4/6 Inhibitors | 8 (47) |

**Table 1: Participant Characteristics (N = 17)**

***Safety***

Because participants had initiated systemic cancer treatment before study entry, pre-existing treatment-related adverse events were documented only if they worsened after study entry; new adverse events, including potential reactions to maitake, were also recorded. No adverse events were reported.

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## RESULTS (CONT.)

| Item | Baseline | Week 4 | Week 8 | Week 12 |
|---|---|---|---|---|
| | *Mean ± SD* | *Mean difference from baseline (95% CI), P value* | | |
| **Neutrophils** | 1.93 ± 1.32 | 0.56 (-0.64 to 1.77), 0.33 | -0.06 (-0.69 to 0.58), 0.85 | N/A |
| **Lymphocytes** | 1.03 ± 0.62 | 0.00 (-0.14 to 0.14), 0.98 | 0.10 (-0.19 to 0.23), 0.85 | N/A |
| **Platelets** | 207 ± 74 | 16 (-11 to 44), 0.21 | 31 (-10 to 72), 0.12 | N/A |
| **NLR** | 2.78 ± 2.15 | 2.42 (-2.48 to 7.31), 0.31 | -0.57 (-1.61 to 0.47), 0.26 | N/A |
| **PLR** | 272 ± 159 | 33 (-88 to 154), 0.56 | -2 (-106 to 102), 0.97 | N/A |
| **CRP** | 3.7 ± 4.8 | -0.3 (-2.8 to 2.2), 0.80 | 0.1 (-0.8 to 1.1), 0.81 | -0.6 (-2.2 to 0.9), 0.39 |
| **Hemoglobin A1c** | 5.6 ± 0.4 | N/A | N/A | -0.1 (-0.3 to 0.0), 0.06 |
| **Quality of life** | 71.6 ± 21.6 | -0.5 (-10.8 to 9.8), 0.92 | 4.6 (-7.5 to 12.2), 0.61 | -0.1 (-11.2 to 11.1), 0.99 |

**Table 2: Results**. SD: Standard deviation; NLR: Neutrophil-lymphocyte ratio; PLR: Platelet-lymphocyte ratio; CRP: C-reactive protein.

**Interpretation**

No consistent trends or clear evidence of change was observed for immune function, inflammation, or quality of life over the 12-week period. Point estimates were small or inconsistent and confidence intervals were wide, indicating substantial uncertainty about the magnitude and direction of any underlying effects. HbA1c remained stable with moderate precision, suggesting the intervention did not substantially change glycemic control in this non-diabetic population. Without a control, we cannot establish whether maitake caused, prevented, or had no effect on outcomes.

**Limitations**

- Results cannot be put into context without a control group
- Heterogeneity in population with regards to treatment type and timing
- Assessments not standardized relative to chemo or CDK4/6 cycles
- Confounding bias – treatments affecting immune function not accounted for

## CONCLUSION

In people with solid tumours receiving chemotherapy or CDK4/6 inhibitors, maitake did not meaningfully affect absolute neutrophil count, other immune parameters, inflammatory markers, or quality of life after 8 and 12 weeks of use. Point estimates were generally small and inconsistent over time, and confidence intervals were wide, indicating substantial uncertainty about any true effect. No adverse events were reported, which supports short-term tolerability in this population. Larger, placebo controlled trials in more homogeneous populations, with assessments timed consistently relative to treatment cycles, are needed.