

Influence of Health Care Professional (HCP) Supervision on Quality of Life (QoL) Questionnaire (QLQ) Scoring by Cancer Patients: A Prospective, Randomized, Cross-over Study (IMSUP)

Abstract ID 387

Nursing, supportive & palliative care, rehabilitation & survivorship

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INTRODUCTION

- ❖ **Systemic assessment of patient-reported outcomes (PROs) can improve the quality of care, outcomes, and patients' QoL, e.g., by the identification of adverse events or areas that need attention.**
 - QoL is also an endpoint in many clinical trials.
- ❖ **QoL is routinely assessed by questionnaires (QLQs) that are increasingly provided digitally for self-completion at home versus HCP-supervised completion on paper.**
 - Advantages include low costs, patient convenience, less time requirements for HCPs, and automated data processing/analysis/reporting; however, response rates are typically lower.
 - Older patients often lack digital skills and access to devices.
- ❖ **QLQs typically assess multiple domains, including sensitive topics like finance- and sexuality-related questions.**
 - Supervised completion may induce bias, particularly for sensitive areas, potentially impacting clinical utility for the individual patient and external validity.

OBJECTIVES

- ❖ **Primary objective:**
 - To study the impact of HCP supervision on scoring patterns on finance- and sexuality-related questions in QLQs by cancer patients receiving systemic antineoplastic therapy, compared to self-administered web-based questionnaires completed at home.
- ❖ **Secondary objectives:**
 - Descriptive analysis of the incidence and characteristics of sexual and financial problems.
 - The impact of HCP supervision on global QoL and scoring patterns on non-sensitive QLQ domains.
 - Patient preference for QLQ completion mode.
 - Response rate, quality of QLQ completion, and HCP time spending as function of completion mode.

KEY INCLUSION CRITERIA

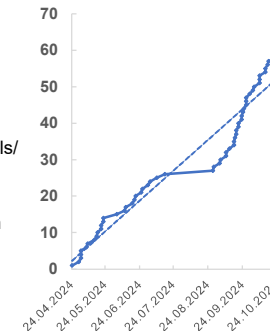
- ✓ Confirmed diagnosis of cancer.
- ✓ Having received ≥ 2 cycles of systemic antineoplastic therapy.
- ✓ Planned to receive ≥ 2 additional cycles of systemic antineoplastic therapy.
- ✓ ≥ 18 years of age.
- ✓ Signed informed consent.
- ✓ Capable to complete QLQs in German.
- ✓ Digital skills and tools to complete web-based QLQs at home.

METHODS

- ❖ **Prospective, randomized, cross-over, open-label, multi-center study (→ Figure 1).**
- ❖ **3 QoL questionnaires are administered:**
 - EORTC QLQ-C30;
 - EORTC QLQ-SH22;
 - A "financial consequences" questionnaire, as routinely used by the social department at St. Claraspital.
- ❖ **Selected demographics, disease characteristics, and treatment-related data are collected from the patient files.**
- ❖ **A sample size of 200 subjects will be recruited yielding 92.8% power to detect an effect size as small as 0.11 points on the QLQ-SH22 scale (interquartile range of 60 points) at an α -level of 0.0166 (corrected for multiple testing).**
 - For each of the 3 QLQs used, the null-hypothesis (H_0) is tested that the method of administration does not influence patients' answers.
- ❖ **Participants are randomized 1:1.**
 - To complete the QLQs on paper under HCP supervision first, followed by digital completion of the QLQs at home before the next cycle ≥ 2 weeks later,
 - or in the opposite order.
 - Stratification factors: gender and center.

RESULTS

- ❖ Recruitment started following Ethical Approval (EKNZ) in April 2024.
 - Recruitment is planned to last 2 years.
 - **61 patients have been included at data cut-off (31 October 2024).**
 - 36 identified potential subjects lacked skills/tools to complete digital QLQs at home.
 - 30 refused participation.
 - 10 were not capable to complete QLQs in German.
 - 19 did not meet other inclusion criteria.
 - for 5 potential subjects not included no specific reason has been documented.



❖ Selected descriptives of included patients (N=61):

- Gender: male 56% / female 44%
- Age: median 66 years (range 33–86 years)
- Marital status: with partner 66% / divorced 18% / single 13% / widowed 3%
- Religion: Christian 43% / other 8% / none 49%
- Tumour type: colorectal 21% / breast 16% / lung 13% / gynaecological 12% / pancreatic 10% / urological 10% / other 18%
- Intent of therapy: palliative 64% / adjuvant 21% / neoadjuvant 18%
- Therapy: chemotherapy 74% / immunotherapy (IO) 10% / non-IO antibody 16%

- ❖ Average age of patients not included due to lacking digital skills/tools (N=36) vs the remaining patients identified (N=125) is 66 vs 76 years:
 - Patients aged < 60 years: 0% vs 25%.
 - Patients aged ≥ 80 years: 42% vs 18%.

DISCUSSION

- ❖ **In this ongoing study (ClinicalTrials.gov: NCT06490393) we investigate whether or not HCP supervision influences QLQ completion rates and scoring by patients, especially in sensitive domains like finance- and sexuality-related questions.**
- ❖ **Recruitment is feasible with 61 patients included thus far.**
- ❖ **Results for the primary outcome are expected Q4/2025 and may guide future studies and QLQ administration strategies.**

FUNDING

- ❖ The IMSUP study is funded by the Dr. Peter Eichenberger Grant, obtained by Diana de Jong.

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Presented at SOHC 2024 in Basel, 20-22 November 2024

Figure 1. Study Design

