Effectiveness of the HuCare Quality Improvement Strategy on health-related quality of life in patients with cancer: study protocol of a stepped wedge cluster randomized controlled trial

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INTRODUCTION

Our group previously demonstrated the feasibility of the Hucare Quality Improvement Strategy - **HQIS**, aimed at integrating into practice 6 psychosocial interventions recommended by international guidelines [1]. This trial will assess whether the introduction of the strategy in oncology wards improves patient Health-related quality of life (HRQoL).

AIMS

The study's primary aim is to evaluate the effectiveness of the **HQIS** vs standard care, in terms of improvement of at least one of the two functional domains of HRQoL, emotional or social, detected at baseline (before treatment initiation) and at clinical follow-up (approximately 3 months after study enrolment).

Secondary aims are:

a) To investigate whether the strategy has an effect on patient mood, in the long-term, on overall HRQoL or specific domains, on specific patient types

b) To measure adherence rate (process indicators), in terms of percentage of clinical staff who complete training and exhibit improvement in their communication skills and percentage of eligible patients who systematically receive the interventions.

STUDY DESIGN

This is a multicenter, incomplete stepped-wedge cluster randomized controlled trial (SWD-CRT), where the intervention strategy is sequentially carried out in three groups of centers (clusters with 5 centers each) and in three equally spaced time periods (epochs) (every 4 months, from the 2nd to 4th epochs). The study also includes an initial epoch, during which none of the centers is exposed to the intervention, and a final epoch when all centers will have implemented the strategy (**Figure 1**). The implementation epoch for each center is randomly assigned, and by the end of the study, all centers will have received the strategy. The intervention is applied at a cluster level, which constitutes the unit of randomization, and assessed at an individual level (on the patients of each cluster) with cross-sectional model (for each epoch, patients are different) [2,3].

STUDY PATIENTS

Cancer patients of any type and stage, who consecutively access the participating centers (outpatient care) during an index period and who fulfill the following inclusion criteria:

- Age > 18
- Diagnosis (histological or cytological) of solid tumor communicated to the patient within the previous two months
- About to start a new medical cancer treatment: chemotherapy (IV or oral), molecular target drugs, hormonal therapy, immunotherapy
- Expected survival > 3 months
- Good comprehension of the Italian language
- Who have read, understood, and signed the informed consent.

Exclusion criteria are:

- Previous chemotherapy or other medical cancer treatment
- Recruited in a previous epoch of the study (that is, patients can only participate during one epoch)
- Currently participating in other trials which imply the completion of Patient Reported Outcomes (PROs) in the same period
- Hospitalized
- Currently receiving psychiatric treatment

Figure 1 - Study design: Stepped Wedge Cluster Randomized Controlled Trial (SWD-CRT)

Centers		Epoch 1 (Months 1-4)	Epoch 2 (Months 5-8)	Epoch 3 (Months 9-12)	Epoch 4 (Months13-16)	Epoch 5 (Months 17-20)
Cluster 1	1	Control	HQIS implementation	Post-Intervention	Post-Intervention	Post-Intervention
	2	Control	HQIS implementation	Post-Intervention	Post-Intervention	Post-Intervention
	3	Control	HQIS implementation	Post-Intervention	Post-Intervention	Post-Intervention
	4	Control	HQIS implementation	Post-Intervention	Post-Intervention	Post-Intervention
	5	Control	HQIS implementation	Post-Intervention	Post-Intervention	Post-Intervention
Cluster 2	6	Control	Control	HQIS implementation	Post-Intervention	Post-Intervention
	7	Control	Control	HQIS implementation	Post-Intervention	Post-Intervention
	8	Control	Control	HQIS implementation	Post-Intervention	Post-Intervention
	9	Control	Control	HQIS implementation	Post-Intervention	Post-Intervention
	10	Control	Control	HQIS implementation	Post-Intervention	Post-Intervention
Cluster 3	11	Control	Control	Control	HQIS implementation	Post-Intervention
	12	Control	Control	Control	HQIS implementation	Post-Intervention
	13	Control	Control	Control	HQIS implementation	Post-Intervention
	14	Control	Control	Control	HQIS implementation	Post-Intervention
	15	Control	Control	Control	HQIS implementation	Post-Intervention

Figure 2 - Hucare Quality Improvement Strategy (HQIS) Flow chart

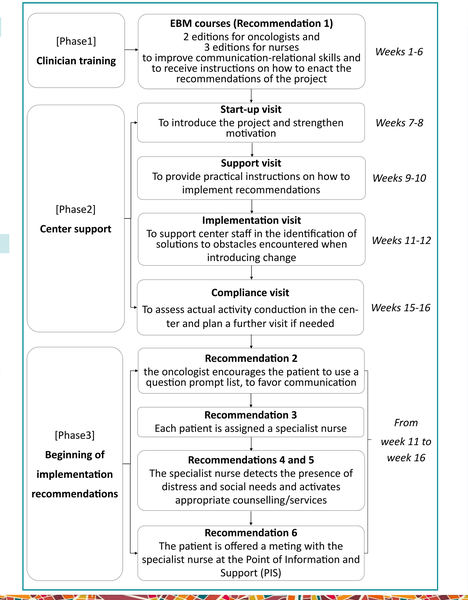

Figure 3 - Schedule of enrolment, interventions, and assessments

Timing	Epoch 1 From months 1 to 4	Epoch 2 From month 5 to 8	Epoch 3 From month 9 to 12	Epoch 4 From month 13 to 16	Epoch 5 From month 17 to 20
Enrolment					
Screening, Informed Consent and Baseline questionnaires - Cluster 1	X		X	X	X
Screening, Informed Consent and Baseline questionnaires - Cluster 2	X	X		X	X
Screening, Informed Consent and Baseline questionnaires - Cluster 3	X	X	X		X
Interventions					
HQIS Implementation - Cluster 1	Control	Implementation	Post-intervention	Post-intervention	Post-intervention
HQIS Implementation - Cluster 2	Control	Control	Implementation	Post-intervention	Post-intervention
HQIS Implementation - Cluster 3	Control	Control	Control	Implementation	Post-intervention
Assessments					
Questionnaires at month 3 Follow-Up - Custer 1	X		X	X	X
Questionnaires at month 3 Follow-Up - Cluster 2	X	X		X	X
Questionnaires at month 3 Follow-Up - Cluster 3	X	X	X		X

Table 1 - The six recommendations of the Hucare Quality Improvement Strategy (HQIS)

Recommendation	Description	Main factors that contributed to choice	How, when and by whom the intervention is implemented
Recommendation 1: Clinician Communication Skills Training	All clinical staff (oncologists and nurses) should attend training designed according to available scientific evidence, to improve their communication-relational skills and to receive instructions on how to enact the five recommendations of the project targeting patients	Communication skills can be taught, and the impact of training is enduring. A Cochrane review shows some positive effects of Communication Skills Training (CST) on health professional communication skills	3-day courses for physicians and nurses (max 20 participants for physicians and 30 for nurses) will be conducted - Role-playing in small groups and interactive material will be used - Each center must ensure that at least 75% of medical staff and of nursing staff operating in the ward complete training
Recommendation 2: Question Prompt List	A Question Prompt List (QPL), list of possible questions that patients may ask their oncologist, must be provided to patients during the initial consultations, and its use encouraged by the oncologist.	QPLs are inexpensive tools which have been shown to increased patient participation in the consultation, . improve communication, patient satisfaction and recall, and possibly decrease anxiety	- The oncologist will provide and introduce the QPL to the patient during the first consultation - The oncologist shall encourage the patient to refer to the QPL at his/her own discretion - A QPL cross-culturally validated into Italian will be used in this study - Encouragement of QPL use, or reasons for not providing the QPL, must be noted in the patient's clinical record
Recommendation 3: Specialist Nurse	A Specialist Nurse (SN) should be assigned to each patient from the first cycle of therapy.	SNs accompany patients through their care, and act as a link with hospital services. Systematic reviews suggest positive effects on patient QoL, satisfaction with care, and psychological outcomes	- Patients will be assigned a specialist nurse at their first access to the center - The oncologist will describe the role of the SN and if possible introduce the SN to the patient - Centers will define the ways in which patients may contact their SN throughout the care pathway
Recommendation 4: Screening for psychological distress	All patients must undergo screening for psychological distress with a validated instrument starting at the initial visits, and those with distress exceeding the threshold value must be referred to psycho-oncological services	Data suggest that screening for and addressing distress not only enhances quality of life but also may be associated with improved cancer outcomes, however distress often goes unrecognized in oncology care. Several organizations, including the NCCN, the Institute of Medicine, and the American Society of Clinical Oncology, have identified the assessment and treatment of psychosocial distress in routine cancer care as a quality care standard	- The Distress Thermometer (DT) [will be provided and introduced to patients by the SN after the first visit with the oncologist and before the first cycle of therapy; - Screening at regular intervals should be ensured to all patients, in particular when they are at greatest risk for distress - DT results will be assessed by specifically trained, qualified personnel of the center - For patients exhibiting distress, psychooncological referral will be ensured, according to a written procedure defined at each center - The DT must be included in the medical record, and any psychooncological referral noted. The psychologist of the ward is responsible for the supervision of questionnaire administration and retrieval, and will ensure assessment
Recommendation 5: Screening for social needs	All patients should undergo screening for social needs with a validated instrument starting at the initial visits, and whenever a need is detected, solutions must be identified.	Evidence suggests several benefits of early recognition and management of needs, such as enhanced quality of care, trust and satisfaction, and improvement in patient–provider communication. Conversely, the failure to address psychosocial problems results in needless patient and family suffering, obstructs quality health care, and can potentially affect the course of the disease and patient experience of cancer	- The Needs Evaluation Questionnaire (NEQ) will be provided and presented to patients by the SN after the first visit with the oncologist and before the first cycle of therapy - Screening at regular intervals should be ensured to all patients, in particular when they are at greatest risk of experiencing social needs - NEQ results will be assessed by the SN or other qualified trained personnel, as defined by each center - For patients exhibiting needs, the appropriate services will be activated by the SN, according to a written procedure defined at each center - The NEQ must be included in the medical record and any activation of services noted
Recommendation 6: Point of Information and Support	All patients must be offered the opportunity to attend a Point of Information and Support (PIS) within the ward.	A PIS is a library for patients and their families, managed by nursing staff trained to inform on issues related to cancer. An RCT conducted by our group showed that when implemented according to the protocol PIS attendance can reduce psychological distress and increase patient Satisfaction	- The PIS must be adjacent to the oncology outpatient or DH area, in a space where privacy is ensured - It must be equipped with internet access and selected information material - All patients must be offered the opportunity to meet their SN at the PIS before treatment initiation and whenever needed

INTERVENTION

The **HQIS** takes 16 weeks to complete (4 months) and comprises three phases, outlined in **Figure 2**. It consists in the introduction of six EBM psychosocial recommendations – 1 targeting clinicians and 5 targeting patients – and in support activities to the centers aimed to favor recommendation uptake. A description of each recommendation, its rationale, and mode of implementation in our project, are provided in **Table 1**. In short, in Phase 1 (lasting approximately 6 weeks) medical and nursing staff of participating centers will attend communication skills training designed according to literature indications (recommendation 1). In Phase 2, the project team will enact activities to support centers in the implementation. These will include provision of reference material and 4 on-site visits by the Improvement Team, composed of personnel not employed at the center (sociologist, psychologist and research nurse). Phase 2 will take approximately 10 weeks. In Phase 3, centers will implement the five psychosocial interventions targeting patients (recommendations 2-6): provision of a question prompt list, assignment of a specialist nurse, screening for psychological distress, screening for social needs, and access to the Point of Information and Support (Table1). This final Phase will last approximately 6 weeks, and will partly coincide with Phase 2.

PARTECIPANT TIMELINE

Patients will be screened and enrolled over 2 consecutive index weeks, to ensure the necessary sample size and representativeness of different cancer types and treatments administered at the centers **(Figure 3)**.

STATISTICAL ANALYSIS

The number of subjects to be enrolled was defined following the methodology for incomplete, cross-sectional Stepped-wedge cluster randomized trials [4]. We calculated an overall sample size of 720 patients, which means 60 patients in each cluster for every detection epoch.

Differences of HRQoL values between the two groups, post intervention and control, relative to each of the two functional domains (emotional or social) of interest for the primary aim, will be analyzed using a binomial Beta regression model (BB), due to the asymmetric value distribution [5,6]. The following covariates will be included in the model: the implementation epoch (first, second or third) and time of exposure to the strategy; the cluster the patient belongs to (1, 2 or 3) and intra-cluster correlation.

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