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BD4QoL BIG DATA FOR QUALITY OF LIFE

708TiP - BD4QoL: A multicenter randomized trial for monitoring quality of life (QoL) by intelligent tools in head and neck cancer (HNC) survivors after curative treatment

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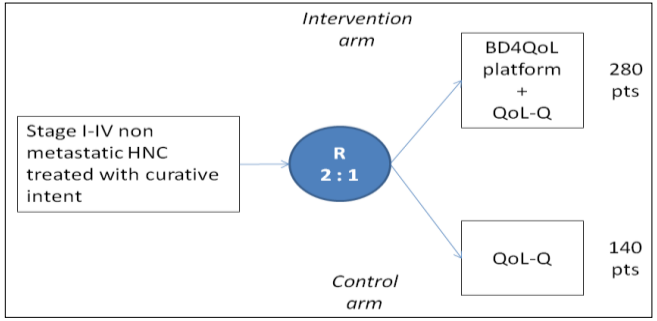
Background

- HNC survivors suffer from high physical, psychological and socioeconomic burdens
- Achieving cancer-free survival with an optimal QoL is the primary goal for HNC pts management. Maintaining lifelong surveillance is critical
- This can be carried out by advanced analysis of environmental, emotional and behavioral data unobtrusively collected from mobile devices
- Aim of this clinical trial: to reduce, with specific non-invasive tools (i.e., personal mobile devices), the proportion of HNC survivors experiencing a clinically meaningful reduction in QoL during post-treatment follow-up



Trial design

- Multicenter, international, randomized (2:1), open-label, superiority trial
- Primary endpoint: clinically meaningful global health-related EORTC QLQ-C30 QoL deterioration (decrease≥10 points) at any point in the timeframe of 24 months post-treatment follow-up
- Sample size: 420 pts
- Patients will be randomized to be followed up using the BD4QoL platform or per standard clinical practice
- The BD4QoL platform includes a set of per project designed services to allow pts monitoring and empowerment through 2 main tools:
- the Point of Care dashboard, to manage and react to pts clinical and tools-generated data and follow-up by clinical investigators
- a mobile application (mApp) installed on participating pts' smartphones, that includes a chatbot for pts e-coaching
- Eligibility criteria
- completing curative treatments for non-metastatic HNC
- the use of an Androidbased smartphone.
- pts undergoing active treatments or with synchronous cancers are excluded.
- In both arms, pts will be followed up as per clinical practice, asked to fill in QoL questionnaires at study entry and during follow-up (every 6 months)

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