Abstract

Background. Numerous publications call for innovation based on integrated care principles, investment in self-management and use of eHealth to improve outcomes for allogeneic Stem Cell Transplant (alloSCT), patients with complex care needs and multiple morbidities. While eHealth supported integrated care models are effective, real-world implementation and sustainability remain elusive. Combining **implementation science with computer and behavioural science methods,** we will implement and evaluate the newly developed **SMILe–Integrated Care Model (SMILe–ICM) for alloSCT patients, aiming to reduce first year post-alloSCT re-hospitalizations**.

The SMILe–ICM is the first theory-based comprehensive eHealth supported integrated care model. Developed by marrying different methodological approaches, it comprehensively addresses alloSCT needs by **optimizing care coordination and care processes, and by reducing response times in cases where the patient's condition is deteriorating at home. SMILe–ICM** includes **four self-management care modules** (i.e., monitoring & follow-up, medication adherence, infection prevention, physical activity) and combines a human role newly embedded in the SCT team, i.e., a Care Coordinator (CC), with a technological component (i.e., the SMILeApp)**.** Patients' symptoms and health behaviours are monitored and transferred, as necessary, to their CC, who supports them in their self-management. Alongside the alloSCT team, the CC manages complications based on care algorithms. Thus, **SMILe–ICM** targets alloSCT patients' clinical and behavioural short- (e.g., infections) and medium-term outcomes (e.g., adherence, treatment burden, GVHD)**.** Our SMILe–ICM pilot work indicates high-level acceptability, feasibility and technological performance.

Purpose. Embedded in **implementation science methodology**, we aim to implement and test the SMILe–ICM at the University Hospital Basel (USB) in the first year post-alloSCT. In addition to targeting one primary outcome, **re-hospitalization rate,** our secondary outcomes will include *effectiveness* (e.g., health care costs, medication adherence**)** and *implementation outcomes (e.g.,* acceptability, fidelity*).* We will also describe and evaluate our *implementation pathway*. Patients will be followed up 3 months after the end of the intervention period.

Methods. A **hybrid 1 effectiveness-implementation randomized controlled trial** will include 80 adult alloSCT patients from the USB Department of Haematology who are transplanted and followed up at USB, have basic German proficiency and elementary computer literacy, and who provide written informed consent. Patients with physical or mental conditions limiting their use of the SMILe–ICM's technology component will be excluded. Approximately ten days before the scheduled alloSCT, a stratified randomization (based on participants' clinical risk scores) will assign patients 1:1 to the control group (CG) or the SMILe–ICM intervention group (IG). The CG will receive usual care; the IG will receive the SMILe–ICM (see above) over one year with 12 scheduled CC visits and continuous use of the SMILeApp. The re-hospitalization rate (primary outcome) and total healthcare utilization costs (payers' perspective) will be assessed using medical records. Medication adherence will be assessed via the BAASIS© scale, treatment burden via the PETS© scale, health-related quality of life via the EQ–5D–5L© (value set for Germany EQ–VT v. 2.0–quality-adjusted life years), and acute and chronic GvHD episodes and survival via medical records. Implementation outcomes will be assessed from both patient and CC perspectives via questionnaires and the implementation pathway via qualitative data collection techniques (i.e., focus groups with patients, clinicians). Quantitative data will be collected using a blinded standardized method in patients' first year post-alloSCT, then 3 months thereafter. Intention-to-treat and per-protocol analyses will be conducted using the rate ratio by unconditional maximum likelihood estimation (Wald) for the primary outcome. Qualitative data will be analysed using mind-mapping techniques and thematic analysis.

Conclusion: The SMILe–ICM implies a systemic innovation in the follow-up care of alloSCT patients, targeting short- and medium-term outcomes. Bolstering patient's self-management, this eHealth-supported behavioural science-driven integrated care approach aims at fast responses to health deterioration. This implementation science methodological innovation will also develop insights regarding the implementation process. Should it prove effective, then, it will also prepare the SMILe-ICM for scaling up or out to other chronically ill patient populations.