Evaluating *ThinkSAFE*: a multi-faceted, collaborative approach to involving patients in improving their own patient safety

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Background: *ThinkSAFE* is an evidence-based, user and theory-informed intervention that promotes a collaborative approach to involving patients and their relatives in improving their safety (Fig 1). The approach addresses environmental constraints, gaps in both patient and professional knowledge, and their respective beliefs about patient involvement. Core components include a theory-based video demonstrating patient safety behaviours, a patient-held logbook incorporating advice for enhancing patient safety and a range of tools to promote information sharing (e.g. medication checklists, a care diary and a question note-pad). Our development work clearly demonstrated that patient and family involvement needs to be actively fostered by staff and that staff require active support to enable them to do this. *ThinkSAFE* therefore includes a staff intervention component in the form of a brief educational session and "talk time" sessions to facilitate patient-professional interactions at key time points along the in-patient pathway (Fig 1).

Study aim: Pre-testing and evaluation of the *ThinkSAFE* approach as recommended by the MRC Framework for the development and evaluation of complex interventions.

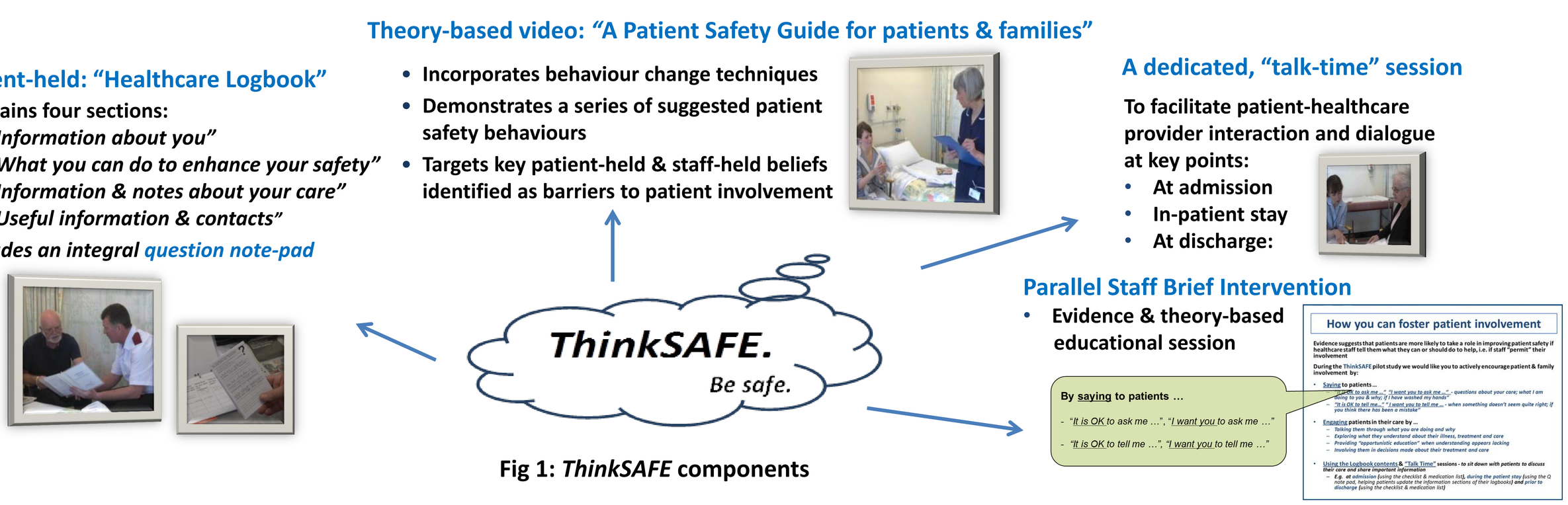

Fig 1: *ThinkSAFE* components

Methods: Controlled, pre-post, exploratory trial, examining feasibility and the potential impact of *ThinkSAFE* on targeted behavioural factors and on improving medication safety. Eight intervention and four control wards took part (acute & elective admissions; surgical & medical specialties). Within a mixed-methods design, theory-based questionnaires measured staff and patient motivation, attitudes, self-efficacy and self-reported behaviour, and a standardised audit tool measured errors in medication reconciliation at admission and discharge. Semi-structured interviews (intervention wards only) explored patient and healthcare professionals' experience.

Findings: Motivation of patients and staff to engage in patient safety behaviours was high. There was no observed impact of *ThinkSAFE* on targeted cognitions for either group, but patients who reported being more involved in their care were also more confident and willing to directly engage with staff about their safety. Regression analyses confirmed that patients' fear of reprisal is a significant barrier to them 'speaking up', lending quantitative support for the core aim and focus of the ThinkSAFE approach. Post-intervention interviews indicated feasibility but the need for adaptability to different settings and preferences; patients reported feeling 'empowered'; and both patients and staff reported more reciprocal engagement in care during interactions. Prescriptions issued on intervention wards at admission were significantly less likely to require pharmacist intervention (a reduction in error rate from 62% to 52%, p=0.033), and where intervention was required, were more likely to contain only one error per patient (73% vs 58%, p=0.024).

Key messages: *ThinkSAFE* is an acceptable, feasible approach that is adaptable to context and user preference. Our findings tentatively suggest a potential to both influence how patients and staff interact, and to improve patient safety. However, patient use of the Logbook and uptake of the promoted patient safety behaviours was dependent on *visible* staff engagement, with 89% patients agreeing (70% strongly) that **staff need to SAY** "its OK to ask …" / "I want you to ask ..." None of the participating wards were able to consistently implement 'talk-time', though individual staff tried to provide opportunities for patient questions during routine care provision. Lack of time and workload burden were commonly cited barriers for not engaging with patients . If staff are to foster patient engagement in their care and safety they themselves require active support and time to enable them to do this.

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