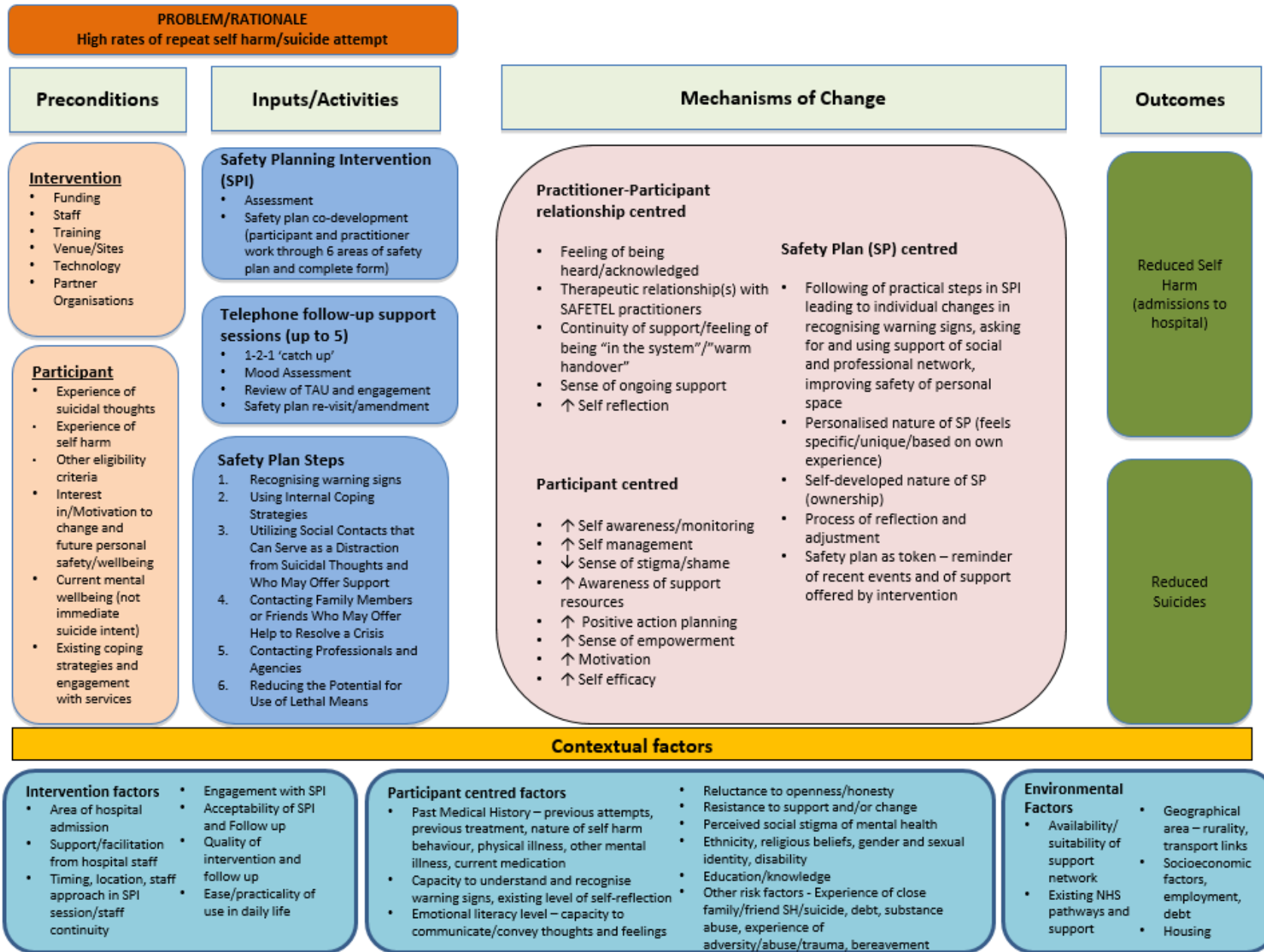


Appendix 1: Proposed logic model SAFETEL study (v5.0 07.06.2018)



Appendix 2: Proposed Progression Criteria SAFETEL study (v1.0 11.06.2018)

CRITERIA	INDICATOR GREEN=Very strong indication to proceed AMBER=Medium indication to proceed. Discuss with TSC and proceed with identified plan to improve performance on indicator in Phase III trial RED=Indication of doubt as to whether to proceed. Discuss with TSC, and only proceed if other indicators are amber/green and there is a clear mitigating strategy	METHOD OF ASSESSMENT
<p>1. Were hospital-based study procedures feasible to deliver and acceptable to staff involved (hospital staff onsite and study staff delivering)? <i>(e.g. referral, recruitment, assessment, SP session delivery)</i></p>	<p>Progression to be agreed in conjunction with Trial Steering Committee (TSC)¹ based on qualitative data captured around experienced and potential barriers to delivery.</p> <ul style="list-style-type: none"> • No current barriers, or those emerging have been minor, planned for and overcome in the past during the course of the feasibility study • Some barriers but for which plans have been made/alternatives prepared • Barriers for which no feasible plan or alternative can be offered/developed 	<p>Qualitative data collected in SAFETEL intervention provider focus groups, and clinical staff interviews, analysed as part of the process evaluation and reported on to the TSC.</p> <p>Barriers identified and changes made to Study Protocol as a result will be reported to TSC.</p> <p>Given the small number of participants offering qualitative feedback, value will be placed on individual reports of barriers, not simply those barriers that are frequently reported by different participants.</p>
<p>2. Were study procedures feasible to deliver and acceptable to participants (including control arm)? <i>(e.g. recruitment, consent/information given, assessment, safety planning session, follow up phone calls)</i></p>	<p>Progression to be agreed in conjunction with Trial Steering Committee (TSC) based on qualitative data captured around experienced and potential barriers to delivery.</p> <ul style="list-style-type: none"> • No current barriers, or those emerging have been minor, planned for and overcome in the past during the course of the feasibility study • Some barriers but for which plans have been made/alternatives prepared • Barriers for which no feasible plan or alternative can be offered/developed 	<p>Qualitative data collected in SAFETEL study participant interviews (intervention and control arms) analysed as part of the process evaluation and reported on to the TSC.</p> <p>Complaints made by participants or relevant Adverse Events will be recorded and reported on to TSC.</p> <p>Given the small number of participants offering qualitative feedback, value will be placed on individual reports of barriers, not simply those barriers that are frequently reported by different</p>

3. Was it feasible to deliver Safety Plan in the hospital?	Feasibility of intervention delivery: <ul style="list-style-type: none"> • Green: > 90% of SAFETY PLANS delivered at hospital • Amber: 60-90% • Red: <60% 	% of safety plans delivered.
4. Was it feasible to deliver 1 st follow up phone call attempt within 72 hours?	Was the progression criterion met? <ul style="list-style-type: none"> • Green: >90% of first calls made within 72 hours of discharge • Amber: 60-90% • Red: <60% 	Feasibility of intervention delivery: % Call attempts made at 1 st follow up phone call time point Was the progression criterion met? % of 1 st Follow up call delivered within 72 hours. Additional qualitative data from SAFETEL intervention provider focus groups, risk log, changes to study protocol identifying barriers and facilitators to implementation reported to TSC.
5. Was the target rate of recruitment and retention achieved? <i>(Are appropriate and effective routes of recruitment available to achieve a powered sample size in a full trial?)</i>	Actual Recruitment rate vs. Target Recruitment rate: <ul style="list-style-type: none"> • Green: >80% of participants • Amber: 60-80% • Red: <60% 	Actual Recruitment rate vs. Target Recruitment rate: Actual participant recruitment rate and target recruitment rate will be measured to support projection of a powered sample for a full trial.
6. Was it feasible to attain a minimum dose target required to justify a full trial?	Adherence rates: <ul style="list-style-type: none"> • Green: >80% • Amber: 60% - 80% • Red: <60% 	Feasibility of attaining minimum dose: % of participants who completed minimum dose participation (i.e. SP+1 Follow up call).
7. Was a target rate of completed baseline measures achieved?	Completion of core measures: <ul style="list-style-type: none"> • Green: >90% data completion • Amber: 70%- 90% • Red: <70% 	Completion of core measures: % of participants completed the core questionnaires. % of missing data from completed core questionnaires.
8. Are identified barriers and challenges to implementation of and adherence to the intervention planned for and surmountable?	Progression to be agreed in conjunction with Trial Steering Committee based on qualitative data captured around experienced and potential barriers to implementation of and adherence to the intervention beyond those already captured in Criteria 1 and 2.	Process Evaluation report. SWOT analysis.

¹ Trial Steering Committee (TSC)

²The Community Health Index (CHI) is a population register, which is used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index.