




Supporting information

Supplementary file 1 a: Summary of the ‘traffic light’ approach for evaluation of the MaCROS study

		
Identifying serious concerns during the qualitative analysis of the participant’s or legal guardian’s interview.	Poor identification of eligible patients.	No issues implementing the study protocol.
Inability to recruit 10 participants within 6 months of the study opening.	Poor recruitment- e.g. fewer than 20 participants recruited.	An adequate number of participants identified and recruited within the 6-month period.
	Problems with delivery/compliance (50-80% of intervention or placebo delivered).	100% compliance with the delivery of the intervention/placebo.
Poor compliance with recording and returning patient diaries (less than 50%).	Poor compliance with recording and returning patient diaries (less than 80%).	Greater than 80% compliance of recording and returning the patient diaries.

Supplementary file 1 b: Findings from evaluating the MaCROS study using the traffic light system from supplementary file 1a.

Aim	Result	Outcome
Implementing protocol	No issues	Proceed
Recruitment	10 participants recruited	Modification required
Identification of eligible participants	Adequate identification of eligible participants	Proceed
Problem with delivery of intervention/placebo	No problems	Proceed
Adherence- probiotic/placebo	80% adherence with completing course	Proceed
Adherence- Completion/adherence of diary	Poor compliance with completion of diary/	Modification required