Figure 2: Participant flow chart

Review all admissions to ABMUHB or CDDFT hospitals1 who are aged $\geq$ 65 years and where consultant has given approval to invite to join study

One or more exclusion criteria; record details

No exclusion criteria

Participant able to consent; discuss study, invite to enroll and provide patient information leaflet

Participant unable to consent; discuss and provide information leaflet to relative / carer

Consent or assent declined; record reason given, if any

Revisit;2 consent obtained

Revisit;2 assent obtained

Allocate next unique identification number from randomized allocation sequence and provide corresponding numbered IMP3

Collect baseline demographic, clinical and quality of life data

Commence intervention; 1 capsule daily for 21 days

Follow up daily during admission and weekly to 8 weeks after stopping antibiotics (maximum 12 weeks) to document
- occurrence of diarrhoea; collect stool sample if diarrhoea develops
- serious adverse events
- quality of life questionnaire at recruitment and 4 and 8 weeks

Withdraw participants who develop pancreatitis or illness requiring high dependency or intensive care. Stop IMP but include data in intention to treat analysis.

Notes

1. ABMUHB – Abertawe Bro Morgannwg University Health Board; CDDFT – County Durham and Darlington NHS Foundation Trust
2. The patient or next of kin is approached for consent in the afternoon if verbal and written information about the trial is provided in the morning, or the following day if provided in the afternoon.
3. Investigational medicinal product; either 21 capsules of probiotic or placebo