CONSULT Case Study

MCA

A randomised controlled trial with care home residents: the PRINCESS trial

BACKGROUND

PRINCESS (Probiotics to reduce antibiotic administration in care home residents) was a randomised controlled trial which ran from 2016-2019 to establish whether or not a combination of two probiotic bacteria, taken each day for up to 1 year, reduced the number of days on which care home residents took antibiotics. Care home residents aged ≥ 65 years were recruited if they were willing and able to give informed consent or, if they lacked capacity to consent, had a consultee to advise about participation on their behalf.

A total of 310 care home residents were recruited from 23 care homes in England and Wales and randomised to receive either a daily capsule containing an oral probiotic combination or placebo. Residents were followed up for 12 months with a review by a research nurse (RN) at 3 months and at 6–12 months post randomisation. The primary outcome was cumulative systemic antibiotic administration days for all-cause infections. Secondary outcomes included incidence and duration of infections, antibiotic-associated diarrhoea, quality of life, and hospitalisations. Care homes were recruited through networks such as ENRICH or directly. Substantial RN support was provided either through RNs employed by the Clinical Trials Units in Cardiff and Oxford who co-ordinated the trial or through the Clinical Research Networks (CRNs).

JUSTIFICATION FOR INCLUDING RESIDENTS WHO LACKED CAPACITY TO CONSENT

A previous observational study by the same research team found that 72% of care home residents lacked capacity to provide informed consent, and that those lacking mental capacity had a higher incidence of infections which were more likely to be serious and harder to treat. This meant that residents who lacked capacity might potentially receive greater benefit from the intervention.

PERSONAL CONSULTEES

If there were concerns about a resident's ability to consent to the trial, a capacity assessment was conducted by the RN. If the assessment confirmed that they lacked capacity to make a decision, a member of care home staff would identify a close relative or friend who could act as a personal consultee on their behalf. They were asked to provide advice to the RN who had the final decision about the resident being recruited.

NOMINATED CONSULTEES

If no relative or friend could be identified who was willing or able to act as personal consultee, a nominated consultee was suggested by the staff at the care home. The nominated consultee could be a member of the care home team who was prepared to be consulted but had no formal involvement with the trial. This meant someone who wasn't carrying out research activities for the trial.

KEY POINTS

Eligibility criteria were kept broad to ensure that the trial was as inclusive as possible.

Consent was considered an ongoing process. If a resident's capacity appeared to change during the trial, a further assessment of their mental capacity in relation to the trial was carried out by the research nurse.

If a resident was assessed to have lost capacity having previously consented to participate, consultee advice was sought regarding their continuing trial participation. The reverse was also applied: if the resident gained capacity, their consent to continue in the trial would be obtained.

The mean age of residents who participated was 85.3 years (SD 7.39). Of the 310 who participated, 33.2% (103/310) were men and 65.8% (204/310) lacked capacity to consent.

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CHALLENGES AND SOLUTIONS

Concerns about including residents who lack capacity to consent
When recruiting care homes, concerns were sometimes expressed by care home managers about the ethical and legal implications of including residents without capacity. A summary of the ethical and legal frameworks was created to share with care homes which detailed how PRINCESS had undergone a rigorous ethical review process and how it complied with the provisions of the Mental Capacity Act 2005.

Maximising residents' ability to provide informed consent
The trial materials were designed to take into account of any age-related sight and hearing loss, conditions affecting mobility or motor skills, or cognitive impairment. These included a pictorial information booklet that the RN could use in place of, or alongside, the participant information sheet during discussions about the trial. The participant information sheet and consent forms were in large print as standard and in A3 in size. The consent process was designed to include the option of verbal consent (witnessed by someone independent of the trial) in the event that residents were unable to provide written consent.

Identifying and contacting personal consultees
Some relatives did not regularly visit the care home, and the trial relied on care homes contacting relatives to provide information about the trial and ask them to complete a consultee declaration form or to be contacted by a RN. Some relatives did not respond which left residents without anyone to represent their wishes. A study amendment was approved to include a timeframe within which a response was anticipated from a personal consultee. The relative was informed that if there was no response within that timeframe then the care home would be asked to nominate a member of the care team to act as a consultee.

Collecting self-reported data
It was anticipated that a sizeable proportion of residents would not be able to complete self-reported outcome measures, or may not be able to do so at the follow-up timepoints. Residents with capacity were asked to self-complete the EQ-5D-5L and ICECAP-O. Care home staff were asked to complete proxy versions for all participants, including those who had capacity. The EQ-5D-5L was amended (with permission) to remove the examples given in the 'usual activities' item ('e.g. work, study, housework, family or leisure activities'), as these were not applicable to the trial population. The no. of residents who self-reported at baseline and follow-up timepoints is available here.

Obtaining biological samples
Samples such as saliva, stool and blood samples were collected at baseline and various timepoints in the trial. Providing samples was entirely optional and residents could participate in the trial without doing so. Explicit statements to this effect were included in the consent and declaration forms. Even with the documented consent/advice in place, if at the time of sampling the participant indicated in any way that they did not wish to do so then sampling was not attempted.

FURTHER DETAILS

PRINCESS was funded by the MRC and National Institute for Health Research (NIHR) EME programme. Information about the project, including the protocol, can be found here: https://www.journalslibrary.nihr.ac.uk/programmes/eme/139510#/

The full project report, including a qualitative study exploring relatives, staff and RNs' views about the implementation of the trial: https://www.journalslibrary.nihr.ac.uk/eme/eme08070#/

A research methods paper exploring the challenges of recruiting residents who lacked capacity to consent: https://methods.sagepub.com/case/controlled-trial-care-homes-challenges-residents-lack-capacity-consent

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