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A realist evaluation of nutritional prehabilitation in adults with acute myeloid leukaemia receiving chemotherapy and or stem cell transplantation

Submission date
21/10/2025

Recruitment status
Recruiting

Registration date
05/01/2026

Overall study status
Ongoing

Last Edited
11/12/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Acute myeloid leukaemia (AML) is the most common type of blood cancer in adults, and survival 5 years after treatment remains low at approximately 15-40% of adults, depending on age. Treatment involves intense chemotherapy with or without a stem cell transplant, and completing all planned treatment is important for survival.

Getting enough nutrition and a variety of nutrients e.g. energy, protein, vitamins and minerals is important for health during and after chemotherapy. About 30% of adults with AML are malnourished at diagnosis and this worsens during chemotherapy. Being malnourished affects a person’s quality of life (QoL) and makes completing and staying well during treatment difficult. Further, those who are malnourished are less likely to survive.

Good nutritional care is clearly important to people with cancer but not always available. Access to nutrition programmes is often based on how malnourished a person is, so the amount of weight or muscle lost or how little a person is eating. However, programmes aren’t designed to prevent or minimise losses before they occur, known as “proactive” care.

Studies show that personalised nutrition programmes given before treatment, delivered alone or as part of a package (i.e., with exercise and/or emotional support) – called 'prehabilitation' may help. The nutritional care delivered in these programmes vary depending on whether a person is malnourished or not. People who are eating well may receive nothing or some information on eating well, whereas those who are malnourished will often receive additional support from a dietitian or other health professional. This additional support may include the prescription of nutrition drinks or products with extra energy, protein and vitamins/minerals.

These proactive nutrition programmes or “nutritional prehabilitation” have been shown to improve treatment completion and outcomes from treatment in other people with cancer. However, studies of “nutritional prehabilitation” in AML are limited and as such how we can improve the nutritional care of people with AML is poorly understood.

Alongside this if a programme is successful in one place, it doesn’t mean it will work if we move it somewhere else, this may be due to differences in the people being treated, the staff and services delivering the care or the local environment. To know how to create programmes that more people can use successfully we need to know how they work, who they work for (or not), and in what situations. This knowledge will help inform how nutrition programmes are designed to meet the needs of different people with AML.

The study will develop a ‘ knowledge model’ informed by patients, carers and other stakeholders that "explains how dietary programmes delivered to adults with AML receiving chemotherapy may work, for whom and in what situations".

Who can participate?
Patients and their carers who have received nutritional advice and care before or during chemotherapy and / or before HSCT, from one of the participating hospitals.

What does the study involve?
1. Develop our understanding: Firstly, the research team have looked at nutrition prehabilitation guidelines and published studies, to develop initial understanding of how these programmes may be working (or not) for whom and in what situations and discussed these with lived experience (AML, carers) and other experts.
2. Test our understanding: Now, we want to know if these understandings hold true in real world nutrition prehabilitation programmes for people with AML undergoing chemotherapy. To do this we will collect different types of data.
a. Collect data from people with AML – through interviews (15-20 people), 5-10 carers of people with AML and nutritional data such as dietary intake, weight, BMI, height already collected during treatment.
b. Collect data from prehabilitation services – through things such as observations, service reports or guidelines to provide information on how the services intend to work, who attended, who provides care and what care was given.
3. Refine our understanding: To bring together the data to refine our understandings of why, for whom and in what situations nutrition prehabilitation programmes work (or not) for adults with AML

What are the potential benefits and risks of participating?
The 'knowledge model' will enable better designed dietary services for people with AML. Through improved nutritional care, adults with AML will feel better during chemotherapy, enabling them to do what's important to them, improving their treatment experience and outcomes.

Where is the study run from?
Nottingham University Hospitals NHS Trust (UK) will act as study sponsors.

When is the study starting and how long is it expected to run for?
April 2024 to December 2026

Who is funding the study?
This study is funded by the National Institute for Health Research, NIHR (UK)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
329722

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR303577

Study information

Scientific Title
Why, for whom and under what circumstances, does nutritional prehabilitation work (or not) to reduce malnutrition in adults with acute myeloid leukaemia receiving chemotherapy and or stem cell transplantation: a realist evaluation

Acronym
NutriPREHAB Study

Study objectives

To develop and test a programme theory that provides insights into why, for whom, and under what circumstances oral nutrition interventions delivered within prehabilitation programmes work (or not) for adults with AML receiving chemotherapy and/ or stem cell transplantation. In order, to inform the design and delivery of future clinical and research programmes of nutritional prehabilitation in this context.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/06/2025, London - Camberwell St Giles Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8256; camberwellstgiles.rec@hra.nhs.uk), ref: 25/PR/0543

Study design
A mixed methods realist evaluation of three nutritional prehabilitation case studies, including realist interviews, quantitative analysis of retrospective clinical and service level data and observations of services

Primary study design
Observational

Study type(s)
Other, Prevention, Quality of life, Treatment

Health condition(s) or problem(s) studied
Nutritional prehabilitation in adults with acute myeloid leukaemia receiving chemotherapy and /or stem cell transplantation

Interventions
Data from a retrospective case note review of dietetic care and cancer treatment; Service delivery materials, Realist interviews of people with AML and their carers to understand their experiences and observations of services will build evidence-informed programme theory. There is no intervention component.

Intervention Type
Other

Primary outcome(s)
Retrospective data is collected from patient records on the their nutritional/dietetic care received, cancer treatment and dates of interventions / treatments. A purposive sample of participants (Patients and carers) are invited to interview to discuss their experiences of nutritional prehabilitation services and how they work, for whom and in what context (via realist interviews). Services are observed (observation diaries) to understand how they are working. All data is pulled together to develop evidence informed programme theories that seek to explain why, for whom and under what circumstances, personalised oral nutrition interventions within prehabilitation for chemotherapy work (or not) in adults with AML. Evidence informed statements describe how different contexts trigger different responses/processes in people or systems (mechanisms) to produce different effects (outcomes) e.g. malnutrition risk or dietary quality.

Key secondary outcome(s))
The outcomes of the programme theory will be achieved by exploring the following collated from retrospective analysis of patient participant health care records during chemotherapy (between diagnosis and stem cell transplantation) and realist interviews (after treatment) and observational diaries of services delivering prehab. Outcomes include:
1. The intended and unintended outcomes of nutrition interventions in different groups of people, e.g.:
1.1. Incidence of malnutrition as measured by validated tools e.g. MUST or diagnostic consensus criteria e.g. GLIM criteria; including % weight change, body mass index, dietary intake (macro and micronutrient), estimated nutritional requirements, presence or absence of sarcopenia, anorexia and/or inflammation, and demographic data (ethnicity, socio-deprivation index, age, sex)
2. Barriers or facilitators to dietary interventions:
2.1. Presence or absence of nutritional impact symptoms e.g nausea, diarrhoea
2.2. Patient and carer experiences of barriers and facilitators via realist interviews
3. Adherence to dietary recommendations/intervention; e.g. nutritional supplement intake, no. of dietetic contacts (planned vs delivered), diet adherence e.g. Mediterranean Diet adherence score (MEDAS) or difference in nutrient intake versus estimated requirements/recommended daily intakes (RDI)
4. Mechanisms by which nutrition interventions interplay with other prehabilitation constituents, where delivered within a multimodal programme (realist interviews/observational diaries)
5. If there are different responses or contextual features required for different people with AML to reduce inequalities in access to these nutritional prehabilitation interventions (realist interviews and retrospective data analysis of medical notes and observations)

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Patient:
1. Diagnosis of either AML or MDS-EB2 (MDS with ≥10% blasts in the bone marrow), or In remission post induction chemotherapy with a plan for further treatment
2. Age ≥16 years, treated on adult AML pathway
3. Receiving active chemotherapy:
3.1. High intensity chemotherapy
3.2. Venetoclax-Azacytidine or
3.3. Azacitidine alone.
3.4. And/or stem cell transplant/ CAR-T therapy
4. Accessed nutritional care as a single prehabilitation intervention or part of multimodal prehabilitation programme

Carer:
Family member or friend, who has provided unpaid* caring duties to a patient (as above) who received nutritional care as part one of the prehabilitation programmes across the 3 case studies.
* this does not preclude those who receive carers benefits from the government.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Patient:
1. Acute promyelocytic leukaemia
2. Age ≤ 16 years old Or ≥ 16 years and treated in a paediatric or Teenage and Young Adult Unit (*Due to the different service provision in these settings)
3. Receiving immunotherapy only OR Not on active treatment e.g. best supportive care interventions such as blood and platelet transfusions only.
4. Received no nutritional care as a single prehabilitation intervention or part of multimodal programme prior to treatment

Carer:
Carer participants: Family member, friend or health professional who has provided paid* caring duties to a patient (as above) who received nutritional care as part one of the prehabilitation programmes across the three case studies.
* this does not include those who receive a carers allowance from the government but are doing it in an employed capacity.

Date of first enrolment
01/11/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Nottingham University Hospitals NHS Trust - City Campus
Nottingham City Hospital
Hucknall Road
Nottingham
England
NG5 1PB

Study participating centre
King's College Hospitals NHS Foundation Trust
Research and Development Office
First Floor, Coldharbour Works
245A Coldharbour Lane
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SW9 8RR

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes