

Personalised prehabilitation in acute myeloid leukaemia

Submission date 15/05/2023	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/05/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/10/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Patients with acute myeloid leukaemia (AML) and myelodysplastic syndrome with excess blasts (MDS-EB2) (types of blood cancer) often present as a medical emergency and require urgent intensive treatment of chemotherapy and in some cases a haematopoietic stem cell transplant (HSCT) for up to 6 months. Patients say that going through this treatment can make them feel very tired (fatigued), have low mood, poor nutrition and be unable to do any exercise. Being able to complete the treatment is very important to improve the chances of survival for people with AML. Programmes that help patients and their carers to prepare for treatment by providing extra information or treatment to improve nutrition, exercise and mood are known as prehabilitation programmes. Currently, prehabilitation prior to chemotherapy or stem cell transplant is not always offered to people with AML or MDS and there is no research in this area. However, research in other cancers for people undergoing surgery has shown that prehabilitation can improve quality of life and survival, reduce tiredness and complications, and help patients complete their treatment. This study aims to see if prehabilitation can help patients with AML or MDS get through all cycles of intensive chemotherapy and HSCT. The researchers are investigating if a prehabilitation prescription that includes remote support for emotional wellbeing, nutrition and exercise can reduce tiredness, improve quality of life, and treatment outcomes for patients with AML or MDS when compared to any prehabilitation that is offered in hospitals now.

Who can participate?

Patients aged 16 years and over with AML or MDS-EB2 in complete remission following induction chemotherapy

What does the study involve?

Participants will be randomly allocated to either:

1. Best practice usual care (control) which is in addition to prehabilitation care received as standard practice at site. It involves a 30-minute virtual prehabilitation discussion with a member of the central team, the participant with or without their caregiver where appropriate, once only as soon as possible following randomisation. It will be based on Maggie's Prehabilitation Guidance and provides the participant with online or printed generic and freely available prehabilitation information on emotional wellbeing, nutrition, and physical activity.

2. Personalised Prehabilitation Care Plan (PPCP) is in addition to prehabilitation care received as standard practice at site. It involves information plus personalised support for emotional wellbeing, nutrition and physical activity. It will be offered as part of each cycle of chemotherapy and HSCT, if given. Where participants are planned to receive long-term lower intensity chemotherapy, this will be offered for the first 3 cycles post randomisation. The PPCP will be developed based on screening and assessment of the person with AML by a central team of prehabilitation experts, with input from local staff and a caregiver (if appropriate). The PPCP will include advice on nutrition, physical activity and managing emotional well-being as required. Additionally, participants will be offered a range of remote support sessions delivered by a central specialist team (psychological wellbeing practitioners with clinical psychologist supervision, clinical exercise physiologist/physiotherapist/ Can-REHAB coaches and dietitians). Local staff will be trained to provide ongoing behavioural support to participants via regular check-ins, to encourage adherence to the intervention.

What are the possible benefits and risks of participating?

We do not know whether the remote prehabilitation care package will improve your quality of life or ability to tolerate treatment, but you may feel more supported, whichever group you are in. You may not directly benefit from taking part in this research, but your participation may provide evidence to help guide treatment in this area in the future for patients with AML or MDS. We do not anticipate there to be any serious risks to you, and we do not expect any patients to come to harm. There is a very small chance exercise can make you feel unwell. Exercise may also cause tiredness, breathlessness and sore muscles, but this should get a bit easier each time you exercise. For your safety, we recommend that you have another person nearby when exercising at home during your first few exercise sessions. During an inpatient stay you may wish to ask a member of staff on your ward to be present or do the session during a visit from a friend or family. Sometimes, people can also find the support sessions upsetting. Our PROPEL specialists are fully trained and will provide appropriate support and assistance if needed.

Where is the study run from?

Warwick Clinical Trials Unit, University of Warwick (UK)

When is the study starting and how long is it expected to run for?

September 2022 to August 2027

Who is funding the study?

National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (UK)

Who is the main contact?

PROPEL@warwick.ac.uk

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-personalised-prehabilitation-for-myeloid-leukaemia-and-myelodysplastic-syndrome>

Study website

<https://warwick.ac.uk/fac/sci/med/research/ctu/trials/propel/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

CPMS 56018, IRAS 320489

Study information**Scientific Title**

PROPEL: Evaluation of PeRsOnalised PrEhabilitation in people with acute myeloid Leukaemia

Acronym

PROPEL

Study objectives

Personalised prehabilitation care package (PPCP) will improve patients' experience of fatigue during treatment in comparison to best practice usual care (BPUC), by supporting patients to manage their emotions, be physically active, and eat an appropriate diet.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 30/05/2023, London – Surrey Borders (Currently being held remotely via Teleconference/ZOOM, London , None available, United Kingdom; +44 (0)207 104 8057; surreyborders.rec@hra.nhs.uk), ref: 3/LO/0347

Study design

Randomized; Interventional; Design type: Treatment, Prevention, Education or Self-Management, Dietary, Psychological & Behavioural, Complex Intervention, Physical, Rehabilitation

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital, Internet/virtual

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Acute myeloid leukaemia (AML)

Interventions

PROPEL is a multicentre, randomised controlled trial comparing best practice usual care (BPUC) with a personalised prehabilitation care package (PPCP) incorporating a 12-month internal pilot, parallel process evaluation and economic evaluation. The aim is to establish the clinical impact and cost-effectiveness of best practice usual care (BPUC) compared to a multiphasic, multimodal personalised prehabilitation care package (PPCP) on fatigue, emotional wellbeing, and quality of life (QoL) in patients in remission following induction chemotherapy. PROPEL plans to recruit 600 participants, who will be randomised on a 1:1 basis.

Patients who are confirmed to be eligible will be invited to take part in the study and if, following a review of the patient information sheet, they decide to participate, written informed consent will be obtained.

Participants will be eligible if they are aged 16 years or over, have a diagnosis of AML or MDS-EB2 and are in complete remission following induction chemotherapy or have relapsed AML for which they have achieved a further complete remission with an intent to deliver further intensive consolidation treatment +/- haematopoietic stem cell transplantation (HSCT).

Baseline: Prior to randomisation, participants will be issued with a baseline questionnaire, they will also be asked to complete a number of assessments including food diaries, a 6-minute walk test, a hand grip strength test, calf circumference as well as providing clinical information.

Participants will be randomised on a 1:1 basis using a computer minimisation algorithm based on the following variables:

1. Age (≤ 60 ; >60 years)

2. Baseline fatigue (none, mild, moderate, severe)
3. Performance status (Karnofsky performance status: 100-80; 70-50; 40-0)
4. Intention to proceed to HSCT (yes; no)

Participants either receive:

1. BPUC: BPUC is a 30-minute virtual prehabilitation discussion with a member of the central team, the participant +/- their caregiver where appropriate, once only and prior to the first cycle of consolidation chemotherapy. It will be based on Maggie's prehabilitation guidance and provides the participant with online or printed generic and freely available prehabilitation information on emotional wellbeing, nutrition, and physical activity.
2. PPCP: PPCP is information plus personalised support for emotional wellbeing, nutrition and physical activity. It will be offered before each consolidation cycle of chemotherapy and HSCT, if given. The PPCP will be developed based on screening and assessment of the person with AML by a central team of prehabilitation experts, with input from local staff and a caregiver (if appropriate). The PPCP will include advice on nutrition, physical activity and managing emotional well-being as required. Additionally, participants will be offered a range of remote support sessions delivered by a central specialist team (psychological wellbeing practitioners with clinical psychologist supervision, clinical Exercise physiologist/ physiotherapist/Can-REHAB coaches and dietitians). Local staff will be trained to provide ongoing behavioural support to participants via regular check-ins, to encourage adherence to the intervention.

PPCP will mirror each consolidation cycle of chemotherapy and HSCT and should commence on day 28 +/- 7 days [post nadir, at least 8 days prior to commencing the next consolidation cycle]. The intervention will continue throughout each cycle and HSCT (if given)

Follow-up: To limit the burden on participants, only primary outcome and key secondary outcome data will be collected prior to each cycle of chemotherapy. Primary and secondary outcomes will be assessed in person at 3 months follow-up post-completion of treatment (either chemotherapy or HSCT) and at 24 months post-randomisation. Follow-up data for relapse and death will be collected for a minimum of 24 months after trial entry and up to 5 years.

Process evaluation: A theoretically informed mixed methods process evaluation consisting of a fidelity and intervention dose assessment across all intervention sites, measurement of any behaviour change differences between intervention and control groups across all sites, and a qualitative interview study focused on six sites. Up to 4 participants per arm, as well as local healthcare professionals (HCPs), key managers and intervention specialists will be interviewed.

Aims: To investigate issues that may affect the delivery and outcomes of the intervention and assess the feasibility of implementing the intervention widely in the NHS

Objectives:

1. To investigate intervention delivery fidelity and impact dose of the PROPEL intervention model.
2. To investigate patients', local site PROPEL Trained HCPs', managers', remote delivery practitioners and central research team multidisciplinary hub members' experiences of the intervention, how and why the intervention did or did not facilitate change among participants, at a sample of six sites, and
3. To explore how the intervention delivery was implemented by the remote delivery practitioners at the sample of six sites and how that implementation affected how the intervention package was delivered and received.

Intervention Type

Behavioural

Primary outcome measure

Subjective levels of fatigue measured using Functional Assessment of Chronic Illness Therapy (FACIT-F) fatigue scale at baseline, following each cycle of treatment, 3 months post EOT and 24 months post randomisation

Secondary outcome measures

1. Emotional wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline, following each cycle of treatment, 3 months post EOT and 24 months post randomisation
2. Anxiety and depression measured using the Patient Health Questionnaire 9-item (PHQ-9) and General Anxiety Disorder 7-item (GAD7) at baseline, following each cycle of treatment, 3 months post EOT and 24 months post randomisation
3. Health-related quality of life measured using FACIT-F and EQ-5D-5L at baseline, following each cycle of treatment, 3 months post EOT and 24 months post randomisation
4. Physical function measured using Karnofsky Performance Scale at baseline, following each cycle of treatment, 3 months post EOT and 24 months post randomisation
5. Physical function measured using 6-min walk test at baseline, 3 months post EOT and 24 months post randomisation
6. Physical function measured using hand grip strength test at baseline, EOT, 3 months post EOT and 24 months post randomisation
7. Presence or absence of sarcopenia measured using SARC-F and calf circumference at baseline, EOT, 3 months post EOT and 24 months post randomisation
8. Incidence of malnutrition and its determinants measured using MUST, percentage weight change; BMI at baseline, following each cycle of treatment, 3 months post EOT and 24 months post randomisation
9. Incidence of malnutrition and its determinants measured using dietary intake from a 3-day food diary at baseline, following each cycle of treatment and 3 months post EOT
10. Completion of treatment cycles assessed using the number of cycles of chemotherapy completed +/- HSCT following each cycle of treatment
11. Onward referrals for 'specialist' services measured using the number of onward referrals to local services for 'specialist' therapies following each cycle of treatment
12. Overall and relapse-free survival assessed using clinical records at up to 5 years post randomisation
13. Readmissions to hospital, ICU admission, number of transfusions, complications of HSCT, adverse events and serious adverse events assessed using clinical hospital records following each cycle of treatment
14. Cost, cost-effectiveness and cost-utility measured using resource use costs, cost and EQ-5D-5L following each cycle of treatment, 3 months post EOT and 24 months post randomisation
15. Process evaluation: fidelity to intervention delivery and dose of intervention received for each component assessed using research records collected throughout the intervention, assessed at the end of intervention delivery
16. Process evaluation: evaluation through qualitative interviews at six sites. 2 sites will be identified during the pilot phase (12 months), with the remaining four identified during the main trial
17. Mechanisms of action: psychological flexibility and motivation measured using CompACT questionnaires and adapted COMB-Q at baseline, following each cycle of treatment, 3 months post EOT and 24 months post randomisation

Overall study start date

01/09/2022

Completion date

31/08/2027

Eligibility

Key inclusion criteria

1. Age \geq 16 years, treated on adult AML pathway

And either:

2. Diagnosis of either AML or MDS-EB2 (MDS with 10% blasts in the bone marrow)

3. In complete remission at the completion of induction chemotherapy (defined $<$ 5% blasts)

4. Intention to undertake consolidation treatment (chemotherapy +/- HSCT)

*Patients undergoing venetoclax-based treatment are only eligible if an HSCT is planned
OR

5. Relapsed AML who have achieved a further complete remission, with an intent to deliver further intensive consolidation treatment +/- HSCT

6. Access to the internet and an email address

7. Willing to use videoconferencing to undertake the appointments and sessions

Participant type(s)

Patient

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

Planned Sample Size: 600; UK Sample Size: 600

Key exclusion criteria

1. Diagnosis of acute promyelocytic leukaemia

2. Undergoing non-intensive treatment (e.g. single-agent azacitidine, low-dose cytarabine)

Date of first enrolment

01/06/2023

Date of final enrolment

31/12/2025

Locations

Countries of recruitment

England

United Kingdom

Wales

Study participating centre

Doncaster Royal Infirmary

Armthorpe Road

Doncaster

United Kingdom

DN2 5LT

Study participating centre

Queen Elizabeth Hospital

Mindelsohn Way

Edgbaston

Birmingham

United Kingdom

B15 2GW

Study participating centre

St James University Hospital

Beckett Street

Leeds

United Kingdom

LS9 7TF

Study participating centre

Rotherham General Hospital

Moorgate Road

Rotherham

United Kingdom

S60 2UD

Study participating centre

Manchester Royal Royal Infirmary

Cobbett House

Oxford Road

Manchester

United Kingdom

M13 9WL

Study participating centre
University Hospitals Coventry & Warwickshire
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Bristol Haematology & Oncology Centre
Horfield Road
Bristol
United Kingdom
BS2 8ED

Study participating centre
Basingstoke and North Hampshire Hospital
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
Northwick Park & St Marks Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre
Clatterbridge Cancer Centre - Liverpool
65 Pembroke PLACE
Liverpool
United Kingdom
L7 8YA

Study participating centre
City Hospital
Dudley Road

Birmingham
United Kingdom
B18 7QH

Study participating centre
Hammersmith Hospital
Du Cane Road
Hammersmith
London
United Kingdom
W12 0HS

Study participating centre
Glan Clwd Hospital
Ysbyty Glan Clwydd
Bodelwyddan
Rhyl
United Kingdom
LL18 5UJ

Study participating centre
Uclh
250 Euston Road
London
United Kingdom
NW1 2PQ

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Wirral University Teaching Hospital
Arrowe Park Road
Wirral
United Kingdom
CH49 5PE

Study participating centre
Royal Hallamshire Hospital
Glossop Road
Sheffield
United Kingdom
S10 2JF

Study participating centre
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Queen Elizabeth Hospital
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Salisbury District Hospital
Salisbury District Hospital
Odstock Road

Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Beatson West of Scotland Cancer Centre
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Victoria Hospital (blackpool)
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
The Royal Marsden Hospital
Fulham Road
London
United Kingdom
SW3 6JJ

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Royal Cornwall Hospital (truliske)
Truliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
Raigmore Hospital
Old Perth Rd
Inverness
United Kingdom
IV2 3UJ

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Kings College Hospital
Denmark Hill

London
United Kingdom
SE5 9RS

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Christie Hospital
550 Wilmslow Road
Withinton
Manchester
United Kingdom
M20 4BX

Study participating centre
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LJ

Study participating centre
Countess of Chester Hospital
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre
Maidstone Hospital
Hermitage Lane

Maidstone
United Kingdom
ME16 9QQ

Study participating centre
St. Bartholomews Hospital
West Smithfield
London
United Kingdom
EC1A 7BE

Study participating centre
Warwick Hospital
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
Basingstoke and North Hampshire Hospital
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
Musgrove Park Hospital
Musgrove Park
Taunton
United Kingdom
TA1 5DA

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation

University of Warwick

Sponsor details

University House
Gibbet Hill Road
Coventry
England
United Kingdom
CV4 7AL
+44 (0)24 765 75733
sponsorship@warwick.ac.uk

Sponsor type

University/education

Website

<http://www2.warwick.ac.uk/>

ROR

<https://ror.org/01a77tt86>

Funder(s)

Funder type

Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR134257

Results and Publications

Publication and dissemination plan

The definitive research findings will be reported via a published HTA monograph (NIHR Library), alongside publications in open-access, high-impact, peer-review journals (trial protocol, primary clinical results, economic evaluation, process evaluation). These will be linked with presentations at relevant conferences, nationally and internationally (haematology and other societies), to which PPI members will be invited within 1 year after the overall study end date.

Intention to publish date

31/08/2028

Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon request through the CI (PROPEL@warwick.ac.uk) after trial publication. A proposal describing the purpose, scope, data items requested, analysis plan and including appropriate acknowledgment of the PROPEL trial management group) should be provided for approval from the PROPEL TMG. Any data transfer would be in accordance with the University of Warwick SOPs and require data sharing /processing agreements to be in place. Participant Consent for future research is requested.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results			12/02/2024	No	Yes