

# Personalised prehabilitation in acute myeloid leukaemia

<b>Submission date</b> 15/05/2023	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/05/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/03/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input 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 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. 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 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 (if given).

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**

Dr Alice Longe

**Contact details**

Warwick Medical School  
University of Warwick  
Coventry  
United Kingdom  
CV4 7AL  
+44 (0)2476 151 661  
Alice.longe@warwick.ac.uk

## 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 ( $\leq 60$ ;  $>60$  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**

31/08/2025

**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**  
**Royal Sussex County Hospital**  
Eastern Road  
Brighton  
United Kingdom  
BN2 5BE

**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**

**Hinchingbrooke Hospital**

Hinchingbrooke Park  
Huntingdon  
United Kingdom  
PE29 6NT

**Study participating centre**

**St Georges Hospital**

Blackshaw Road  
Tooting  
London  
United Kingdom  
SW17 0QT

**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**  
**Freeman Road Hospital**  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**  
**Great Western Hospital**  
Marlborough Road  
Swindon  
United Kingdom  
SN3 6BB

**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**  
**Stoke Mandeville Hospital**  
Mandeville Road  
Aylesbury  
United Kingdom  
HP21 8AL

**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

## **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?
<a href="#">Plain English results</a>			12/02/2024	No	Yes