Health Research Authority

Qualitative Protocol Development Tool

The research protocol forms an essential part of a research project. It is a full description of the research study and will act as a 'manual' for members of the research team to ensure adherence to the methods outlined. As the study gets underway, it can then be used to monitor the study's progress and evaluate its outcomes.

The protocol should go into as much detail about the research project as possible, to enable the review bodies to fully understand your study.

The use of this collated consensus guidance and template is not mandatory. The guidance and template are published as standards to encourage and enable responsible research.

The document will:

- Support researchers developing protocols where the sponsor does not already use a template
- Support sponsors wishing to develop template protocols in line with national guidance
- Support sponsors to review their existing protocol template to ensure that it is in line with national guidance.

A protocol which contains all the elements that review bodies consider is less likely to be delayed during the review process because there will be less likelihood that the review body will require clarification from the applicant.

We would appreciate self-declaration of how you've used this template so we are able to measure its uptake.

Please indicate the compatibility of this template with any existing templates you already use by stating one of the following on the front of each submitted protocol:

- **This protocol has regard for the HRA guidance and order of content; OR**
- **This protocol has regard for the HRA guidance; OR**
- **This protocol does not have regard to the HRA guidance and order of content**

SHORT TITLE/ACRONYM

FULL/LONG TITLE OF THE STUDY

Take5Care+: A self-management educational intervention to support the haematology patients' journey following a neoplastic diagnosis.

SHORT STUDY TITLE / ACRONYM

Take5Care+

PROTOCOL VERSION NUMBER AND DATE

1.3 (final version for submission) – 8/5/2026

RESEARCH REFERENCE NUMBERS

IRAS Number:	368667
SPONSORS Number:	1257
FUNDERS Number:	N/A

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:
.....

Date:
...../...../.....

Name (please print):
.....

Position:
.....

Chief Investigator:

Signature:
.....

Date:
...../...../.....

Name: (please print):
.....

LIST of CONTENTS

SHORT TITLE/ACRONYM

KEY STUDY CONTACTS

Chief Investigator	Jitka Vseteckova, jitka.vseteckova@open.ac.uk
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Sponsor	The Open University (Mark Brandon, research-rec-review@open.ac.uk)
Joint-sponsor(s)/co-sponsor(s)	Northampton General Hospital (NGH) (Michelle Spinks, michelle.spinks1@nhs.net)
Funder(s)	Northamptonshire Health Charity
Key Protocol Contributors	Sinead Eccles, sinead.eccles@open.ac.uk Yannis Pappas, yannis.pappas@beds.ac.uk Nicole Andelic, nicole.andelic@open.ac.uk
Committees	Faculty – Jitka to confirm with the Associate Dean the title of the Faculty committee

STUDY SUMMARY & ACRONYMS

This study is a feasibility trial using the Take Five model (with co-produced actions with PPI group) as a self-managed intervention for individuals who have recently been diagnosed with a haematological cancer to improve feelings of control, management and health and well-being.

Acronyms:

CI: Chief Investigator
DCP: Data Collection Point
NGH: Northampton General Hospital
NGHRN: Northampton General Hospital Research Nurse
OU: Open University
OURA: Open University Research Associate
PI: Principal Investigator
PIS: Patient/Participant Information Sheet
UoB: University of Bedfordshire

Study Title	Take5Care+: A self-management educational intervention to support the haematology patients' journey following a neoplastic diagnosis.
Internal ref. no. (or short title)	Take5Care+
Study Design	30-day self-managed intervention with follow-up

SHORT TITLE/ACRONYM

Study Participants	Recently diagnosed haematology patients at Northampton General Hospital
Planned Size of Sample (if applicable)	20
Follow up duration (if applicable)	Three months post-intervention
Planned Study Period	24 months including recruitment and follow-up
Research Question/Aim(s)	Main aim: 1. To assess the feasibility of using Take5Care+ with patients newly diagnosed with indolent or chronic haematological malignancies managed with active monitoring or non-intensive treatment, recruited via hospital departments **(Aim 1)** Secondary aims: 2. To assess the impact of participating in Take5Care+ on patients' self-reported health and well-being, healthy behaviours and sense of control, knowledge and management of health **(Aim 2)** 3. Explore perceptions of patients and clinicians about their participation in Take5Care+ **(Aim 3)**

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Northamptonshire Health Charity Springfield, Cliftonville, Northampton, NN1 5BE Tel: 01604626927 Email: greenheart@nhcf.co.uk	**Details of financial support** £50 000
UoB support in kind	
Dr Georgia Papageorgiou – support in-kind	

ROLE OF STUDY SPONSOR AND FUNDER

The study sponsor is the Open University who are responsible for study design (in co-production with the participants), conduct, data analysis and interpretation, manuscript writing and dissemination.

The Northamptonshire Health Charity is the source of the funding, provided by a private donor with lived experience of the haematology diagnosis, who reviewed the original proposal and advised on changes. The funder does not control final decision regarding any aspects of the study.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Advisory Group

An Advisory Group consisting of members listed below, chaired by Dr Alner. Members will have experience of conducting research in this field and/or clinical practice and will have full overview of the protocols and related materials. The project team will attend each meeting.

Dr Victoria Alner (Consultant Physician in Geriatric Medicine, Milton Keynes University Hospital)

Dr Erica Cook (Associate Professor, UoB)

Professor Alison Fox (Professor, OU)

Dr Fani Liapi (Senior Research Fellow, UoB)

Professor Yannis Pappas (Professor, UoB)

Dr Andrew Nicholds (Clinician, NGH)

Dr Sanhita Chakrabarti (Deputy Chief Medical Officer, Bedfordshire, Luton and Milton Keynes Integrated Care Board)

Victoria Rodgers (Macmillan Lymphoma Clinical Nurse Specialist, NGH)

Yasmin Al-Azzawi (Lead Nurse for Haematology, Milton Keynes University Hospital)

Professor Lindsay O'Dell (Professor, OU)

Patient & Public Involvement Group

There is currently no official PPI group existing in NGH so we will set up a PPI group consisting of 4-6 patients who have previously been diagnosed with haematological cancer, with similar characteristics to the participant sample group. This group will help us to co-design and co-produce the shape of Take5Care+.

The group will be asked to offer their views on two areas: 1) the list of actions (see attachment "List of actions" and 2) the remote support that is available (e.g. number of emails, content in emails, phone calls from the OURA) during Take5Care+.

The PPI group will ensure that the program is suitable for patients who have been diagnosed with indolent or chronic haematological malignancies managed with active monitoring or non-intensive treatment and that any actions/support offered that are not suitable are removed from the list.

A PPIE application will be submitted to the Open University Human Research Ethics Committee as an amendment to this application.

SHORT TITLE/ACRONYM

PROTOCOL CONTRIBUTORS

Nicole Andelic (design, conduct, data collection, data analysis, report & manuscript writing, dissemination)

Jitka Vseteckova (design, conduct, data analysis, report& manuscript writing, dissemination)

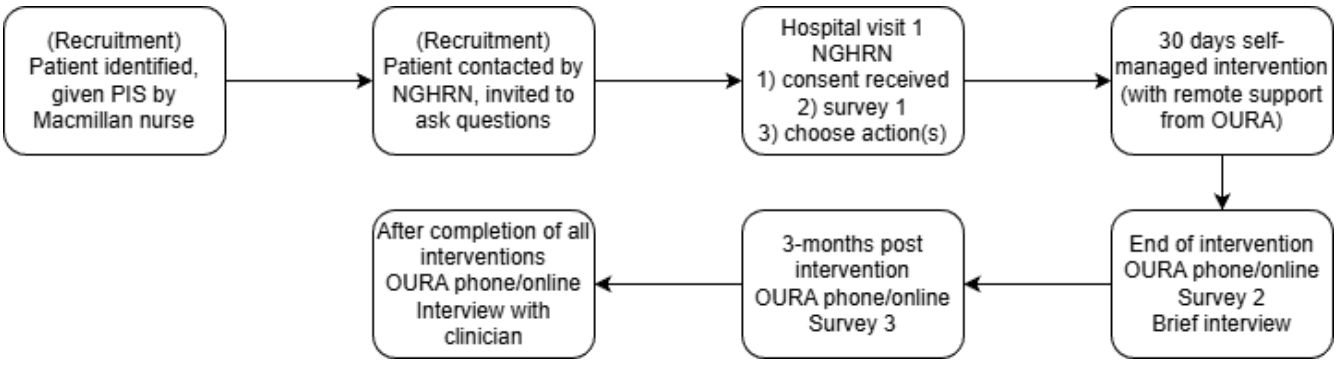
Sinead Eccles (design, conduct, data analysis, manuscript writing, dissemination)

Yannis Pappas (design, data analysis, manuscript writing)

Georgia Papageorgiou (design, conduct, data analysis, manuscript writing, dissemination)

KEY WORDS: Health literacy, low-grade haematological cancer, healthy lifestyle, self-management, participatory approaches, secondary prevention

STUDY FLOW CHART



SHORT TITLE/ACRONYM

STUDY PROTOCOL

Take5Care+: An innovative intervention to support the haematology patients' journey following a neoplastic diagnosis.

1 BACKGROUND

Take Five to Age Well (Take Five) was designed to empower people to achieve effective, long-term self-management by becoming partners in becoming and staying healthy by introducing 'bite- size', everyday actions that are available to all. Our experience from implementing Take Five across the four nations is that it is exceptionally timely in addressing prevention needs at individual and system levels. In its first, pilot iteration, over 3,200 people (members of the public without a specific diagnosis) made the Take Five pledge/challenge and engaged in guided healthier behaviours.

Transitioning between acute and community care services is a complex process and often carries a risk of subsequent readmission(s) (Naylor et al., 2011). This is especially likely when the patients are also dealing with long-term and/or terminal conditions; they are likely to feel weaker, not resilient, and possibly not recovering as expected, and often with decreased confidence to self-manage when at home. There are clear indicators, based on our research work, that Take Five in 2023 (adopted by over 3000 participants), similarly to other pledges/challenges (Dry January etc), support the ageing public in creating healthy habits through a 30-day commitment in an easy and engaging way (Vseteckova, 2024). The Take Five model also has the potential to support those who might be transitioning between acute and community services as it supports the creation of habits that can help us stay strong, sharp, independent, feel better, and/or support our recovery journey when being long-term ill, injured, and/or hospitalised.

In addition, there is evidence to suggest that when people are being diagnosed and or admitted to/discharged from the hospital, there is a window of opportunity that health psychologists call the 'teachable moment' (Buchbinder et al., 2014; Pétré et al., 2020), meaning that people may at this point be more open to actions that may lead to behavioural change. Take Five is designed to improve sense of control and management of health, especially when receiving a diagnosis of a long-term and life-limiting condition.

2 RATIONALE

Patients who are diagnosed with indolent or chronic haematological malignancies may feel that they have little or no control over their health which can be distressing. Patients with a haematology diagnosis in particular often spend many years being actively monitored before treatment is required and the uncertainty of the trajectory adds to the anxiety of these patients (McCaughan et al., 2023). However, a diagnosis or medical "trigger" can also be the opportunity for a "teachable moment" during which patients are more likely to open to behaviour change, which can positively impact on their health and wellbeing.

By recruiting newly diagnosed haematology patients to take part in a self-managed behaviour change intervention, we aim to empower and improve the perceived control over health and well-being for patients who are either being actively monitored or only on non-intensive treatment. Improved control, in turn, can improve self-management of health conditions (Ludman et al., 2013).

The Take5Care+ intervention includes behavioural actions which are flexible and accessible, but importantly this study will include a list of actions which is co-produced with a PPI group to ensure that it is suitable for this patient subgroup.

The proposed assessment of feasibility will inform the future recruitment of hospitals and patients into a larger definitive trial.

3 THEORETICAL FRAMEWORK

This is a study exploring the feasibility and acceptability of using an intervention modelled in the style of a "pledge" (Chaintarli et al., 2016; de Visser & Piper, 2020) delivered at the time of a "teachable moment" (Pétré et al., 2020). A teachable moment is a point during which people may be more open to actions that lead to behavioural change. For behaviours related to health, there is evidence suggesting that the teachable moments are likely to occur when people are diagnosed or admitted to/discharged from the hospital (Buchbinder et al., 2014; Pétré et al., 2020). The current study targets individuals with a diagnosis of indolent or chronic haematological malignancies who are either placed on a monitoring list or offered low-intensive therapies. For these individuals, who are likely to be monitored for many years, it is particularly important that their health is optimised during this time as there are studies which demonstrate a link between healthy behaviour, particularly physical activity, and improved quality of life and reduced anxiety (Miles et al., 2025).

Take5Care+ uses a challenge, or a "pledge" to improve behaviour in one or more areas of health. Previous research has found evidence that taking part in pledges can lead to beneficial outcomes. For example, there is some evidence that Dry January leads to overall improvements in general health and reduced problematic drinking (de Visser, 2016; de Visser et al., 2016) and that years with higher Stoptober campaign budgets were associated with a larger number of quitting smoking attempts (Kuipers et al., 2020). In addition to the pledge, Take5Care+ includes a learning component via brief, informative emails throughout the pledge. Learning contributes to maintaining good physical and mental health while ageing (Balyasnikova et al., 2025; Balyasnikova et al., under review).

4 RESEARCH AIMS

Main aim:

1. To assess the feasibility of using Take5Care+ with patients newly diagnosed with indolent or chronic haematological malignancies managed with active monitoring or non-intensive treatment, recruited via hospital departments **(Aim 1)**

Secondary aims:

2. To assess the impact of participating in Take5Care+ on patients' self-reported health and well-being, healthy behaviours and sense of control, knowledge and management of health **(Aim 2)**
3. To explore the perceptions of patients and clinicians about their participation in the Take5Care+ **(Aim 3)**

4.1 Objectives

Aim 1: Feasibility

1. Establish the feasibility of recruiting a sufficient number of patients within a reasonable timescale for a definitive trial via recruitment logs, study attrition and survey attrition
2. Determine an effect size by calculating the difference between end-of-challenge and baseline data and standard deviation for these for each of the outcomes (Section 4.2 Outcomes: Aim 2). The effect size will be used to inform power calculations for future trial
3. Explore the feasibility of recruiting and retaining clinicians in the study via qualitative interviews
4. Explore the acceptability of Take5Care+ for patients and clinicians via anonymised hospital data and qualitative interviews with patients and clinicians

Aim 2: Impact of Take5Care+

1. Measure primary outcomes (health, well-being, sense of control, knowledge and management of health) and compare baseline and end-of-challenge using self-assessed and self-reported variables (Take5 Survey and SF-12)
2. Measure and compare adherence to actions at end-of-challenge and at three-months follow-up using self-reported variables

Aim 3: Explore perceptions

1. Explore the experience of participating in Take5Care+ for patients via qualitative interviews
2. Explore the barriers and facilitators (e.g. actions offered, remote support offered) for patients and clinicians via qualitative interviews

4.2 Outcome

Aim 1: Feasibility

- Anonymised data of recruitment numbers within the six-month timescale
- Study attrition via study logs
- Survey attrition (Take5 Survey and SF-12)
- Optional semi-structured interviews with participants (Data Collection Point 2; DCP2)
- Qualitative interviews with healthcare professionals (DCP3)

Aim 2: Impact of Take5Care+

Self-reported measures of health and healthy behaviour (Take5 Survey and SF-12)

- Self-reported behaviours that facilitate improved nutrition, hydration, physical activity, cognitive stimulation and social engagement (DCP1, DCP2 and DCP3)
- Self-reported health as measured by SF-12 (DCP1, DCP2 and DCP3)
- Self-reported adherence to Take5Care+ actions (DCP2 and DCP3)

Subjective perception of health (Take5 Survey)

- Perceived control over health (DCP1, DCP2 and DCP3)
- Perceived knowledge of how to maintain health (DCP1, DCP2 and DCP3)
- Perceived ability to manage health (DCP1, DCP2 and DCP3)

Aim 3: Explore perceptions of patients and clinicians

- Thematic analysis of perceptions of participation, barriers and facilitators via semi-structured interviews with patients (optional, DCP2) and clinicians (DCP3)

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

This is primarily a feasibility study assessing participant recruitment, study attrition, survey attrition and exploring patient and clinician experience to inform main trials in the future. In addition to this there are secondary objectives including measuring self-reported health and wellbeing (SF-12), health behaviours, perceived control, knowledge and management of health (Take5 Survey) before and after taking part in the challenge, as well as a qualitative element exploring perceptions of taking part in the challenge.

SF-12 is a validated scale assessing health-related quality of life and producing a Physical Component Summary and a Mental Component Summary, ranging from 0-100. It is a 12-item brief version of the SF-36, to reduce burden on the respondent. The Take5 Survey questions were used in the 2023 and 2025 Take Five challenge. There are approximately 30 questions in each survey. Items assessing health behaviour use 7-point Likert frequency scale measures (1=never, 7=every day), whereas items assessing attitudes are formatted as 5-point Likert scale measures (1=None/Awful/Much less/Strongly disagree, 5=A great deal/Excellent/Much more/Strongly agree), with the exception of three items in Survey 1 and eight items in Survey 2 and 3 that use 7-point Likert scales (1=Very difficult/No control/False/Strongly disagree, 7=Very easy/Complete control/True/Strongly Agree). The survey has remained the same as in Take Five 2023 and 2025 to allow for comparisons of summary data (means and standard deviations) across the different populations.

Data will be collected by the NGHRN and the OURA, see brackets after each data collection point.

The study will start in July 2026 and finish when all data collection required to answer the research questions have been completed. Participant recruitment will be on-going for 6 months, starting in July 2026 and finishing in December 2026. Participants recruited to the study will be asked to choose at least one action and commit to it for 30 consecutive days. They will also be asked to complete three surveys; at baseline (Survey 1), directly after the 30-day challenge (Survey 2) and three months after challenge completion (Survey 3). Survey 2 will also ask if they are interested in taking part in a brief (15-20 minutes) interview exploring their perceptions of taking part in the study.

If a patient is interested, the Macmillan nurse will share Participant Information Sheet (PIS) and pass contact details on to NGHRN. The patient will be contacted a few days later by the NGHRN and if patient wants to participate they will then come to the hospital for visit 1 (DCP1) to:

- Give consent (NGHRN)
- Choose day of study start (day 1 of 30-day challenge) (NGHRN)
- Choose the action(s) to complete for 30 days (NGHRN)

- Choose the way they want to be/don't want to be contacted (they will all receive 2 emails per week and if they wish we will offer one phone call or text from the OURA) and support offered (as tailored with PPI group but may consist of OURA emails, AI coach, OURA phone calls) (NGHRN)
- Complete baseline data collection (Take5 Survey 1 + SF-12) (NGHRN)

They will then begin the challenge/intervention. The daily action will differ depending on the chosen action but will consist of one the following (actions may be removed from this list if advised to do so by the PPI group):

1. *Breakfast: have a healthy breakfast every day*
2. *Eat regularly everyday*
3. *What works for you – do it everyday (e.g. cut down on sugar)*
4. *Drink enough water: stay well hydrated everyday*
5. *Reduce your alcohol intake: try a month without alcohol*
6. *Carry a water bottle: keep a water bottle with you when you leave home*
7. *Walk for your health: go for two short walks every day, you know your ability so decide the distance that works for you.*
8. *Get outside for five minutes every day: breathe and take in the outdoors*
9. *Power: do 3 short (6-10 min) bursts of weight bearing exercise every day*
10. *Stand: Get up and move for 5 or more minutes every hour throughout the day*
11. *Stay flexible: every couple of hours you are sitting, do two minutes of stretching and moving*
12. *Connect: call or meet a friend or family member for a chat every day*
13. *Know your community or neighbours and engage with someone everyday*
14. *Share a hobby: try a new hobby with others*
15. *Learn: learn or do something new, practice daily and perhaps share it with others*
16. *Get creative: draw something everyday – you could do this with a grandchild or swap pictures about your day with a friend.*
17. *Play: do puzzles and play games every day*
18. *Be mindful: pause and take notice of your surroundings for at least 1 minute, 3 times a day*
19. *Read – hug your brain with a nice book by reading at least 5 pages a day*
20. *Write about your day - keep a daily journal*

At the end of the 30 days (DCP2) the participants will:

- complete an end-of-challenge questionnaire (Take5 Survey 2 + SF-12) (online/phone with OURA)
- *optional*: complete a 15-20 min interview (online/phone with OURA)

Three months after the end of intervention (DCP3) the participants will:

- Complete a three-month follow-up questionnaire (Take5 Survey 3 + SF-12) (online/phone with OURA)

The surveys will take approximately 20 minutes to complete.

Additional secondary data will be collected, including:

- a recruitment log (over 6 consecutive months)
- study attrition rate and survey attrition rate
- short (20 min) online/phone semi-structured interviews with the clinicians involved in the study at the end of Take5Care+. These will be identified and approached via the NGHRN using the study log, but if interested, the details will be passed on to the OURA who will receive consent and conduct the interview. (NGHRN/OURA)

If the participants need help filling out the surveys, the NGHRN or OURA can assist them. They can also ask a family member, friend or a carer if they wish. This has been reiterated at the start of each survey (see attached surveys). As this is a feasibility study, funding is unfortunately limited and it is not possible to make further adjustments for accessibility, for example for hearing impaired, visually impaired or non-English speaking patients. However, the findings from this study will inform a larger main trial, which will take these considerations into account.

Analysis plan:

Feasibility will be assessed through descriptive statistical summaries of recruitment numbers over the six-month period (via study logs), study attrition (via study logs) and survey attrition (via survey completion rates). Semi-structured interviews will be transcribed, anonymised and analysed using thematic analysis by the OURA.

Impact of the challenge will be assessed through comparison of descriptive statistical summaries (means, standard deviations) of self-reported measures of health and health-related behaviours and subjective perception of health. Due to the low sample size the study is unlikely to have enough statistical power to test the significance of any potential difference before and after the challenge. However, in the event that there is a moderate-large effect size, the measures will be analysed using within-group t-test by the OURA.

Perceptions of patients and clinicians will be explored through semi-structured interviews that will be transcribed, anonymised and analysed using thematic analysis by the OURA.

Data will be processed (anonymised) and digitally encrypted and stored by the Sponsor organisation (The Open University) up to ten years after study completion. Only the named researchers will have access to the data.

6 STUDY SETTING

Participants will be recruited via haematology consultants and the research nurse at NGH. The initial data collection point (DCP1) consists of giving consent, completing baseline data collection (Take5 Survey 1 + SF-12) and choosing an intervention action and it will take place at NGH (see section 5).

The intervention is self-managed and does not require any site visits.

DCP2 (Take5 Survey 2, SF-12 and optional interview) and DCP3 (Take5 Survey 3 and SF-12) will take place online/over phone and do not require any site visits (see section 5).

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

Patients invited to the study will be newly diagnosed (within 3 months).

The patient group will include patients diagnosed with a chronic or indolent haematological malignancy on active monitoring or non-intensive oral anti-cancer therapy. Primarily, this group will consist of patients diagnosed with the following conditions (as outpatients):

- low grade lymphoproliferative disorders (low grade lymphoma, CLL) – included only if they are on an active monitoring programme or non-intensive oral anti-cancer therapy.
- indolent myeloma- included only if they are on an active monitoring programme or non-intensive oral anti-cancer therapy.

Table 1. Current pool of participants before exclusion criteria has been applied

ICD		N diagnosed in past 6 months
C820-C823	Follicular Lymphoma	5
C829	Follicular Lymphoma unspecified	3
C830	Small cell B-cell lymphoma	2
C831	Mantle Cell Lymphoma	4
C851	B-cell Lymphoma – unspecified	8
C880	Waldenstrom Macroglobulinaemia	3
C884	Extranodal Marginal Zone Lymphoma	2
C900	Multiple Myeloma	9
C911	Chronic Lymphocytic Leukaemia	13
C931	Chronic Myelomonocytic Leukaemia	3
C921	Chronic Myeloid Leukaemia	0
D45X	Polycythaemia Vera	5
D467	Other Myelodysplastic syndromes	1
D469	Myelodysplastic Syndrome, unspecified	2
D471	Chronic Myeloproliferative Disease	2
D473	Essential Thrombocythemia	9

D474	Myelofibrosis	2

The conditions outlined above represent clusters of chronic and ongoing types of blood cancer conditions, where standard care includes active monitoring or non-intensive oral anti-cancer therapy.

7.1.1 Inclusion criteria

- 18 years or older.
- Have been diagnosed within the last 3 months with one of the eligible conditions listed in Table 1.
- Be managed with either:
  - Active monitoring, or
  - Non-intensive oral therapy, defined as outpatient oral regimens that do not require inpatient initiation and have lower expected toxicity (e.g., BTK inhibitors, TKIs, interferon, lenalidomide, hydroxycarbamide, low-dose alkylators).
- Have ECOG Performance Status 0–2.
- Be able to give informed consent.
- Be judged suitable for participation by the treating clinician.

7.1.2 Exclusion criteria

- Receiving intensive chemotherapy, immunotherapy, IV combination regimens, cellular therapy, radiotherapy or treatments requiring inpatient initiation.
- Received or expected to require regular blood product transfusions
- Life expectancy <12 months.
- Acutely terminal illness.
- ECOG ≥3.
- Cognitive impairment that would prevent the patient from giving informed consent, or reliably completing the daily action and follow-up assessments
- Pregnant or lactating.
- Currently participating in a CTIMP or other behavioural research intervention.
- Age <18.
- Unstable, uncontrolled, or severe comorbidities:
  - Uncontrolled heart failure, unstable angina, or MI <3 months.
  - Stroke/TIA <3 months.
  - Severe/unstable COPD or asthma with recent exacerbations.
  - Poorly controlled diabetes
  - Severe psychiatric illness interfering with participation.
- Concurrent active malignancy requiring systemic therapy.
- Any other condition that, in the investigator's judgement, would compromise safe participation.

7.2 Sampling

The sample size will be restricted as there are a limited number of patients to study. Therefore, the whole population (all eligible participants who are not excluded by clinical criteria as described at 7.1.2) will be invited to participate in the study (convenience sample). At the time of application the pool of potential participants before applying exclusion criteria is 73 patients (Table 1). These numbers may differ at the

time of the study as some of these patients will no longer be newly diagnosed and others may have been added to the list of potential patients. To balance the need for a sufficiently large sample size whilst also completing the study in a timely manner, recruitment will take place over 6 months so that newly diagnosed patients during this timeframe can be invited before closing recruitment.

7.2.1 Size of sample

All eligible participants will be informed and invited to take part in the study. The sample size will be determined by eligibility and uptake rate. As this is a feasibility trial there are no previous studies that can inform uptake rate and study recruitment will therefore take place over 6 months to maximise the sample size. The target sample is 20 participants but more may be accepted depending on the time and resources that are available.

7.2.2 Sampling technique

The sample will be a convenience sample, due to the eligibility criteria. The aim of the study is to explore the feasibility of using the Take Five framework to manage behavioural changes in a population who has recently been diagnosed but are either being monitored or undergoing low-intensive treatment. To ensure that the co-produced materials are appropriate for the study population, a specific diagnosis has been chosen (indolent or chronic haematological malignancies managed with active monitoring or non-intensive treatment). This limits the number of eligible participants but ensures that the study has been co-produced with patients with this particular lived experience.

7.3 Recruitment

Patients:

1. If a patient is eligible, the consultant notifies the Macmillan nurse following the sharing of the diagnosis with the patient.
2. After usual care, the Macmillan nurse asks patient if they are interested in receiving a Participant Information Sheet for Take5+Care and if they would like to speak to the NGHRN.
3. If patient says yes, Macmillan nurse also asks about the preferred ways to be contacted and puts them in touch with the NGHRN (who will then notify the OURA)
4. NGHRN will contact the patient (copying OURA and explaining their role in the project) a few days later to tell them about the study and what is needed from them. The patient will be offered more time to think about the study or if the patient is interested in taking part in the study, a hospital visit will be organised for the patient to give consent and complete baseline measures with the NGHRN.

Clinicians (interviews):

1. Any clinicians who are involved in the project will be identified and approached by the NGHRN via the study log. At this point a PIS for clinicians will be shared.

2. If the clinician is interested in participating, their contact details will be shared with the OURA

3. At the time of the online interview, electronic consent will be received by the OURA during the videocall.

7.3.1 Sample identification

The haematologist will identify participants after diagnosis and refer any eligible participants (using the eligibility criteria above) to the Macmillan nurse to discuss the study during their standard care meeting. Although participants can get travel expenses reimbursed, no other payment is included. This is described in the Participant Information Sheet.

7.3.2 Consent

If a patient agrees to take part in project (after being contacted by NGHRN and having had sufficient time to consider the Participant Information Sheet), they are then asked to come to the hospital for consent to be given by completing the consent form as well as completion of all baseline measures/survey items (NGHRN). Consent will be reviewed at every point of contact with the participant. Participants can apply to the OU to get travel expenses reimbursed for this one in-person meeting.

8 ETHICAL AND REGULATORY CONSIDERATIONS

A PPI group will be involved in co-designing and co-producing the actions and support offered during Take5Care+, ensuring that specific needs/considerations of the sample are taken into account. All participants who meet the eligibility criteria outlined in section 7 will be invited to take part in the study.

Informed and voluntary consent will be received from all participants prior to taking part in the study. The Participant Information Sheet will be shared with participants in advance. Consent will be reviewed at every point of contact with the patient (in person, online or over phone) and participants have the right to withdraw from the study at any point but we will keep any data that has already been collected. At the start of each survey the arrangements for consent and withdrawal rights have been reiterated.

All data will be anonymised and stored in an encrypted file only accessible to those named in section 8.8. Personally identifiable information kept for contact reasons throughout the study (e.g. name and contact details) will be kept separately from the study data in a secure and encrypted file and only accessible to those named in section 8.8. All anonymised data will be removed ten years after study completion. Participants will be informed prior to taking part that summaries of the data and anonymised quotes may be disseminated in academic and non-academic publications/presentations/reports.

The participant eligibility criteria have been carefully developed by clinicians to ensure that those who meet the inclusion criteria are fit to participate in the study. As the patients have a medical condition, care has been taken to ensure that the surveys/interview questions are not likely to be distressing and unlikely to be cognitively demanding. The majority of the data collection will be carried out remotely to avoid travel. If patients at any point during the study disclose feeling physically or mentally unwell they

will be directed to the clinical care team. Furthermore, the proposed intervention actions will be reviewed by both patients (in the PPI group) and clinicians to ensure that they carry low risk.

The study will not commence until it has been approved by The Open University HREC and received full ethical approval by REC and IRAS. Any substantial amendment to the protocol will be reviewed by IRAS.

8.1 Assessment and management of risk

All safeguarding concerns will be included in the site log. In the event of distress the research team will follow the Open University distress policy, inform the CI and the clinician. The PIS includes a statement informing participants that if there is a disclosure of harm the research team member will have to disclose it to the clinical care team.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

The study will receive Open University HREC approval, NHS ethical review (REC) and regulatory approval from HRA (via IRAS) prior to start of study. The ethical review will include the study protocol, Participant Information Sheet, consent forms, surveys and consultant script used for recruitment.

Any substantial amendments will be created via IRAS.

All correspondence with the NHS REC will be retained. The Chief Investigator will produce an annual progress report (APR) within 30 days of the anniversary date on which the favourable opinion was given and annually until the study is completed. If the study ends prematurely, the Chief Investigator will notify the REC and include reason for the premature termination. Within one year of the study completion the Chief Investigator will submit a final report (including any publications or abstracts) to the NHS REC.

Regulatory Review & Compliance

The CI/PI will ensure that appropriate approvals from NGH are in place prior to enrolling participants.

For any amendment to the study the CI (or designee) will submit information to NHS REC/IRAS for them to issue approval for the amendment. The CI/designee will work with NGH to ensure that necessary arrangements are put in place to implement the amendment.

Amendments

The CI will decide when an amendment is required and whether it is a substantial or non-substantial amendment. If a substantial amendment is required, the Open University (the CI) will submit a notice of amendment to the NHS REC for consideration and notify the lead NHS R&D for the county as well as the R&D office and local research team at NGH.

If a non-substantial amendment is required, the CI will notify NHS R&D in case of change to funding arrangements.

In any case of an amendment, all affected documents (study protocol, consent form, Participant Information Sheet) will be updated with the new amendment clearly highlighted in the text and with a new version. All amendments will be included in the study log.

8.3 Peer review

Protocol has been reviewed by an external clinician and an external researcher with background in the relevant area, both members of the Advisory Group.

8.4 Patient & Public Involvement

Patients and clinicians will be actively involved in the acceptability and design of the research. The PPI group consists of patients with a haematological cancer diagnosis. They will comment on the day-to-day administration of the programme, including support offered (emails, confidential online platform, Whatsapp coach) and the available intervention actions.

The feasibility of the intervention will be evaluated through short interviews with patients (if they consent to it) and clinicians after the 30-day challenge has been completed.

8.5 Protocol compliance

A site log will be the responsibility of the PI (but managed by the research nurse) and available to the research team. The site log will be securely stored in NGH during the study duration. Any deviations, non-compliances or breaches from the protocol will be documented in the site log and reported to the CI immediately. Any frequently occurring deviations from protocol will be actioned immediately by the CI.

8.6 Data protection and patient confidentiality

All participants will generate a unique ID to maintain confidentiality. The unique ID will only be linked to personal information (such as contact details necessary to access participants) in an encrypted, password-protected file, separate from all other data collected for the study. The column with contact details will be destroyed after the study has been completed. Only the named researchers will have access to the data collected in the study. Consent forms will be kept separately from all other study data. The participant information sheets will include information on how the data is used.

Interviews with patients and clinicians will be audio-recorded and transcribed by a member of the research team (OURA). Audio recordings will be kept separately and securely until the transcriptions have been verified and analysis is completed. After this the recordings will be destroyed. Transcriptions will be anonymised.

The surveys will ask participants to create a unique identifier when completing the first survey. This unique identifier will be used to link the three surveys with each other, and it will be stored in the recruitment log, separately from the research data, for the duration of the study in the unlikely case it is needed to identify a participant disclosing harm in a survey. However, upon study completion it will be removed from the recruitment log and it will only be used to link the three surveys together.

There will be summary data about number of recruited patients from total available patient population and drop-out rates (numerical only) collected from study logs. This data will not include personal identifiable data.

All study data excluding the file with contact details and the original interview recordings but including PIS, consent forms, data responses and site logs, master logs and delegation logs will be stored at the OU for a duration of ten years after which it will be destroyed. During this time the consent form will be kept securely and separate from the research study data.

All investigators and study site staff will comply with the requirements of the Data Protection Act/UK GDPR (2018) and amendments with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. The Sponsor (The Open University) is the Controller of all study data and will store this data for ten years after study completion. The Site (NGH) is the Sponsor's Processor. All data protection and confidentiality arrangements will undergo an Open University Data Protection assessment and approval prior to starting data collection.

8.7 Indemnity

NGH is covered by NHS Indemnity scheme. The Open University has indemnity insurance that will cover liabilities arising from the participation in the study. Details are set out in the Model Agreement for Non-Commercial Research. The Open University will not provide no-fault compensation to participants in the unlikely event of harm due to taking part in the study for which negligence cannot be demonstrated.

8.8 Access to the final study dataset

The named researchers will have access to the final dataset:

Dr Nicole Andelic, The Open University

Dr Jitka Vseteckova, The Open University

Dr Sinead Eccles, The Open University

9 DISSEMINIATION POLICY

9.1 Dissemination policy

The data will be owned by the Open University. Upon completion of the study, the data will be analysed and tabulated and a final study report will be prepared accessible from the project website (on open.ac.uk). The study report may partly or wholly be submitted for publication in an appropriate peer-reviewed journal at a latter stage.

On the consent form, participants will be given the opportunity to 'opt-in' to receiving an e-mail with a study debrief upon completion of the study. If so, their e-mail address will be stored separately to the rest of the data and deleted after the debrief has been disseminated.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Any individuals who have made substantial contributions to the conception, design, acquisition, analysis or interpretation of the data; drafting or revising the work; final approval of the version; agreement to be accountable for all aspects of the work will be included as authors of the final study report. Those who do not meet all four criteria will be acknowledged.

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11. APPENDICIES

11.1 Appendix 1- Required documentation

CI CV

Participant Information Sheet (challenge +surveys)

Participant Information Sheet (interviews)

Participant Consent Form (challenge + surveys)

Participant Consent Form (interviews)

Clinician Participant Information Sheet

Clinician Participant Consent Form

Survey 1

Survey 2/3

SF-12

Take Five actions (to be confirmed with PPI group)

Post-intervention interview guide for patients

Post-intervention interview guide for clinicians

Review 1

Review 2

Costing template

Evidence of sponsor insurance or indemnity

11.2 Appendix 2 – Schedule of Procedures (Example)

	Screening (in person during regular appointment)	**Baseline (in person)**	**End of challenge (remotely)**	**Three months follow-up (remotely)**
PIS	x			
Informed consent		x		
Demographics		x		
Medical history (if applicable)		x		
Action		x	x	

Take5 Survey, SF-12		x	x	x
Adherence to Take5Care+ (intervention)			x	x
Interview with patients			x	
Interview with clinicians				x

The process and data collection points will be as follows: The consultant refers the patient to the Macmillan nurse following the sharing of the diagnosis with the patient.

The Macmillan nurse will complete usual care and then offer patient a Participant Information Sheet for Take5Care+. If patients are interested, the nurse will ask about preferred way to be contacted by the NGHRN and share patient's contact details with NGHRN.

NGHRN will contact patient to confirm that they want to participant and invite patient to hospital for consent. When patient returns to hospital for visit 1, patient gives their consent, completes baseline questionnaire and chooses action for the Take5Care+ intervention.

Throughout intervention participant will be supported by OURA remotely (frequency and mode of support co-designed with PPI group).

At the end-of-challenge, OURA will contact participant to complete Survey 2 (Take5 Survey + SF-12). Participant can choose to also complete a short interview (15-20 mins).

At three-months follow-up, OURA will contact participant to complete Survey 3 (Take5 Survey + SF-12). OURA will also interview all clinicians involved with the study (20 mins).

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.