PROTOCOL

FULL STUDY TITLE:

Acceptability and preliminary effectiveness of a mobile health intervention (Untire app) for adult cancer patients and survivors with cancer related fatigue: A pilot clinical study

SHORT TRIAL TITLE:

Acceptability of an updated version of the Untire mHealth app.

RESEARCH REFERENCE NUMBERS

IRAS Number: 318755

Clinical trials.gov Number: [not yet assigned]

REC reference: **23/YH/0101**

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

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 clinical investigation without the prior written consent of the Sponsor

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

For and on behalf of the Trial Sponsor:

Signature: Date:

..../...../.....

Name (please print):

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Position:

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Chief Investigator:

Signature: Date:

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Name: (please print):

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STUDY SUMMARY

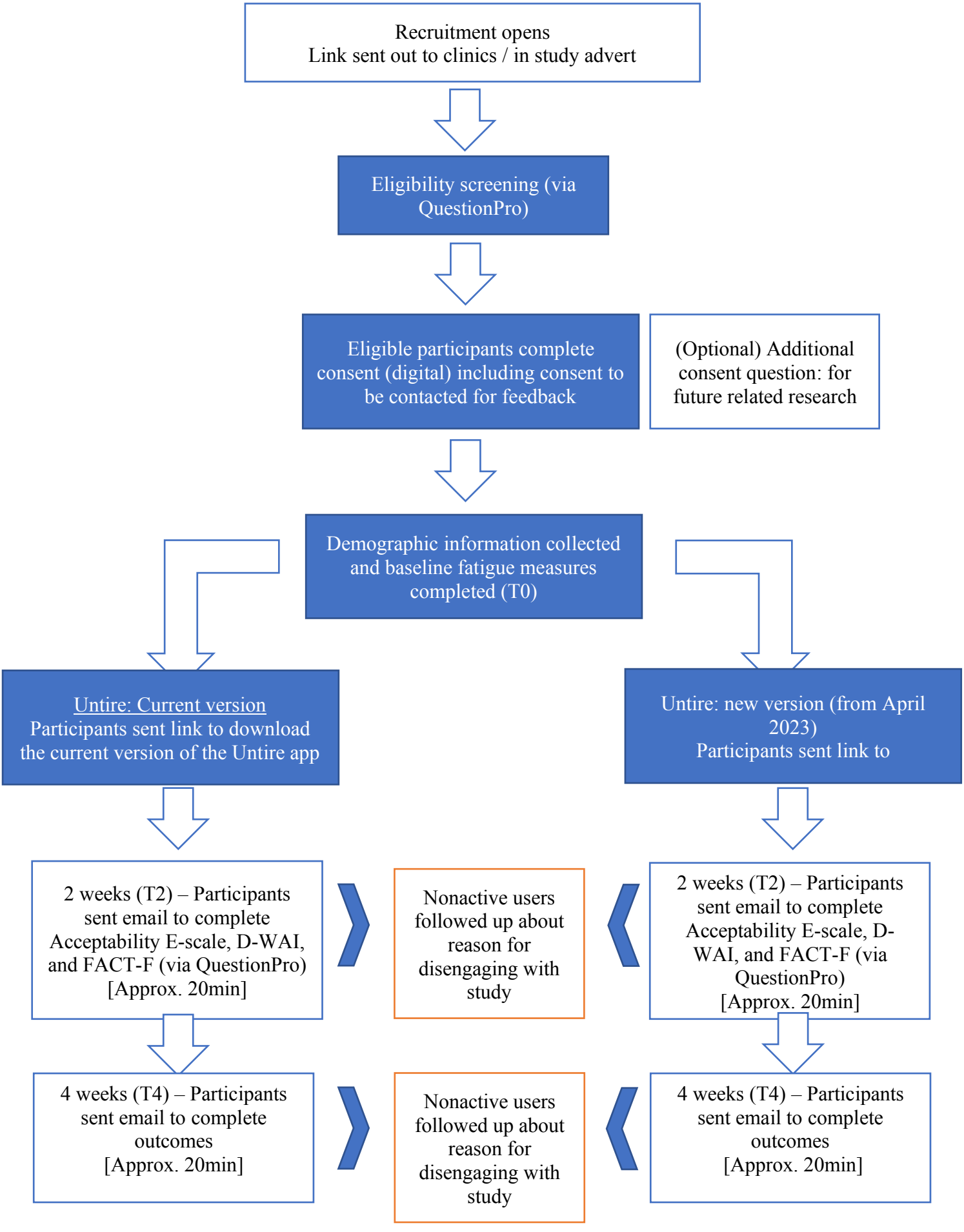
Study Title	Acceptability and preliminary effectiveness of a mobile health intervention (Untire app) for adult cancer patients and survivors with cancer related fatigue: A pilot clinical study
Short title	Acceptability of an updated version of the Untire mHealth app.
Study Design	A between groups study design
Study Participants	- Adult (18 years and older) - Currently receiving treatment from cancer or cancer survivors of any cancer type. - A moderate or severe level of fatigue (self-report).
Planned Size of Sample (if applicable)	110 participants (55 in each group).
Planned Study Period	12 week study period with outcome measures collected at baseline, 2 weeks (T2), 4 weeks (T4), 6 weeks (T6) and 12 weeks (T12).

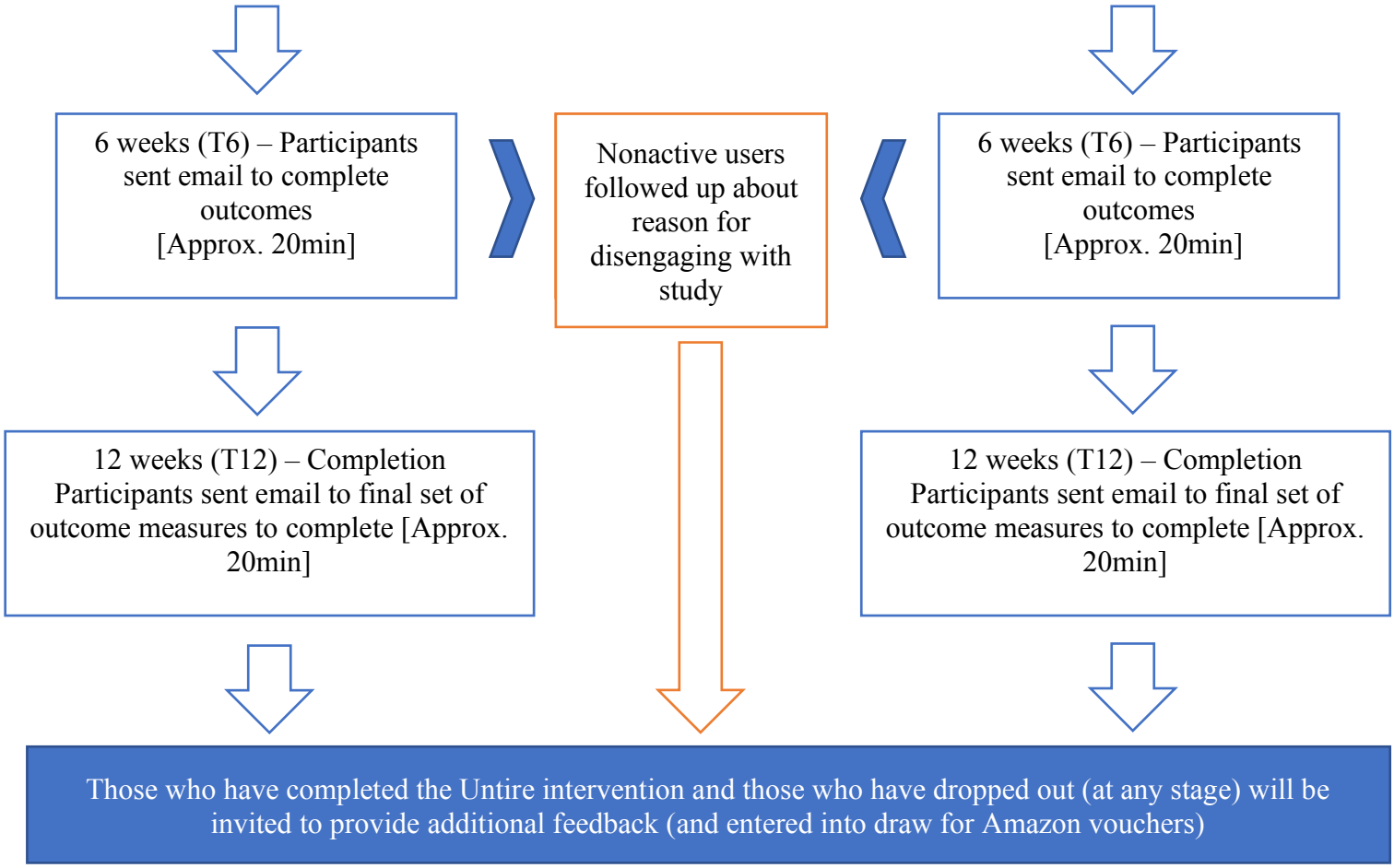
Research Question/Aim(s)	The aim of this study will be to assess the engagement and acceptability of the Untire mHealth intervention for adults with cancer related fatigue. We will aim to compare engagement and acceptability between the current version of the (Untire app) and the newer version of the app (due to be released in April 2023). A secondary aim of this study will be to provide preliminary efficacy outcomes of the Untire intervention in reducing fatigue and QoL in adults experiencing cancer related fatigue.

ROLE OF STUDY SPONSOR

The University of Bath with be the sponsor of this study and assume overall responsibility for the initiation and management of the study.

STUDY FLOW CHART




6 weeks (T6) – Participants sent email to complete outcomes [Approx. 20min]
Nonactive users followed up about reason for disengaging with study
6 weeks (T6) – Participants sent email to complete outcomes [Approx. 20min]
12 weeks (T12) – Completion Participants sent email to final set of outcome measures to complete [Approx. 20min]
12 weeks (T12) – Completion Participants sent email to final set of outcome measures to complete [Approx. 20min]
Those who have completed the Untire intervention and those who have dropped out (at any stage) will be invited to provide additional feedback (and entered into draw for Amazon vouchers)

Background / Literature Review

One of the most severe and commonly reported side effects from cancer treatment is cancer-related fatigue (CRF) (Minton et al., 2013; Bray et al., 2018). The National Comprehensive Cancer Network (NCCN) had defined CRF as a 'distressing, persistent, subjective, sense of physical, emotional and/or cognitive tiredness or exhaustion' which is 'not proportionate to recent activity and significantly interferes with usual functioning' (Bower et al., 2014). CRF is reported as one of the most distressing symptoms related to cancer (Stone et al., 2000) and it is strongly associated with reduced patient satisfaction and health related quality of life (Charalambous & Kouta, 2016).

The CRF prevalence rate ranges from 50-90% across all ages, dependant on cancer diagnosis (Weis J., 2011; Campos et al., 2011). Teenagers and Young Adults (TYA) diagnosed with cancer experience CRF at similar rates to adults, but it has been suggested that the impact of severe fatigue is more pronounced as it interferes with important developmental milestones such as education, employment, and establishing relationships (Poort et al., 2017). CRF has been associated with higher levels of psychological distress (anxiety and depression) in TYA with cancer (Nowe et al., 2018).

CRF is a multifaceted problem which involves a complex interaction of physiological, biochemical, and psychological systems. Cognitive behavioural models have been used to conceptualise the symptom of fatigue (both its onset and continuance) in various health conditions (Browne and Chalder, 2006, Gielissen et al, 2007, Van den Akker et al., 2018). Cognitive Behavioural Therapy (CBT) aims to reduce fatigue symptoms by focusing on fatigue related cognitions (increased symptoms focus, beliefs that activity will increase fatigue) and behaviours (prolonged rest, poor sleep hygiene) perpetuating fatigue symptoms.
There is a growing evidence base for the effectiveness of psychosocial interventions, such as CBT, in reducing symptoms of fatigue in cancer patients and survivors (Gielissen et al., 2007). Poort and colleagues (2020) demonstrated that CBT was effective at reducing cancer related fatigue in adults. Another trial demonstrated the

effectiveness of integrating CBT with graded exercise in improving fatigue and functional outcomes (Sandler et al., 2017). Both trials were in an adult population (Mean ages of 51.2, SD=9.5 and 62.8, SD=9.35 respectively) and generally there has been limited research into interventions for fatigue in TYA living with cancer (Spathis et al, 2015). TYA are typically offered no or, minimal, interventions (exercise, rest) for fatigue (Spathis et al., 2017).

Although tailored psychosocial interventions have been shown to be effective in treating adult CRF, the reach of these interventions are limited to being delivered individually or as a group (Sandler et al., 2017). Given the prevalence of CRF and increased service pressure, there is a growing need for self-management resources and interventions to help support cancer survivors (Stout et al., 2016).

The use of eHealth (online) and mHealth (mobile phone, app) interventions has expanded rapidly in recent years (Lewis et al., 2016). They provide several benefits beyond traditional psychosocial interventions, such as overcoming logistical barriers and reduced therapeutic costs (Marcolino et al., 2018). The COVID-19 pandemic highlighted the additional need for services to adapt interventions and utilise digital technologies for remote service delivery (Verma & Mishra, 2020). mHealth interventions are likely to be particularly relevant for TYA. This population are generally more technologically literate with 88% of teenager and 98% of young adults using mobile devices to connect to the internet (Lenhart, 2015). These interventions also align with TYA preferences for using technology to access health related support and information (Abrol et al., 2017).

There is a growing body of evidence suggesting that mHealth interventions are effective in supporting fatigue self-management in adult cancer survivors (Hernandez Silva et al., 2019). For TYA cancer survivors, digital interventions are increasingly being developed to support symptom management and behavioural change (McCann et al., 2019). Initial positive findings from an mHealth app have demonstrated an increase in health-related quality of life among TYA with cancer (Pappot et al., 2019). Despite the increasing development of smart phone apps for TYA with cancer and the initial positive findings in terms of support and self-

management, no apps have yet been developed specifically for managing fatigue in TYA cancer survivors.

One mHealth intervention that has been developed to support cancer patients and survivors with CRF is Tired of Cancer's Untire app (https://tiredofcancerapp.com). This self-management app, developed in the Netherlands, is based on clinically supported evidence for patients with CRF. The app is comprised of four modules (i.e. My Themes, My Exercise, Physical Activity, and Tips) that patients work through in their own time. These modules draw on psychological principles of CBT, psycho education and mindfulness-based stress reduction (MBSR) to help address dysfunctional thoughts and stress along with exercises to help improve physical activity.

A large-scale, waiting-list randomised, control trial demonstrated the Untire app was effective at reducing fatigue and improving quality of life (QoL) in adults with CRF (Spahrkäs et al., 2020a). This initial trial showed promising findings that an mHealth intervention can be an effective treatment for CRF. The mean age of the participants within the original trial was 55 years old (SD=9.79) with few younger adults recruited. Therefore, it is difficult to ascertain whether the Untire app would be a suitably acceptable intervention in a TYA cancer population. The original Untire trial only implemented online recruitment, which may have accounted for the specific sample characteristics seen in the trial (older adults and mainly female, 91%) (Spahrkäs et al., 2020b). Further research may look to broaden recruitment strategies (including NHS health care settings) to increase the reach of the app.

A limitation of the above trial, and other studies involving remotely delivered mHealth interventions, is that high drop-out rates and decreasing app use are common (Anguera et al., 2015). Due to study design and methodologies, it is often not always possible to determine the reasons for why participants have dropped out of these studies. This information could be useful to researchers in further developing mHealth interventions more generally and improve acceptability to specific populations (TYA).

Research on mHealth app development has suggested that personalisation of user experience is particularly important for maintaining patient engagement for long-term use (Madeira et al., 2018). A new version of the Untire app is currently under development (S. Spahrkäs, personal communication, March 30, 2022) which incorporates additional themes that are personalised to the user.

Another factor considered fundamental in the success of any psychological intervention is therapeutic alliance (TA). The role of TA is rarely considered in digital health interventions (Tremain et al., 2020), but given that the use of mHealth interventions is increasing, further exploration of the role of TA in how users engage with mHealth apps is important.

Aims and Hypotheses

The aim of this study will be to assess the engagement and acceptability of the Untire mHealth intervention for adults with cancer related fatigue.

We will aim to compare engagement and acceptability between the current version of the (Untire app) and the newer version of the app (due to be released in December 2022).

Further within group analysis will be conducted to compare level of engagement and acceptability between TYA (18-30) and adult (30 and above) participants in our sample.

A secondary aim of this study will be to provide preliminary efficacy outcomes of the Untire intervention in reducing fatigue and QoL in adults experiencing cancer related fatigue. The hypotheses for these efficacy outcomes are:

Hypothesis 1: Participants using the Untire app intervention will show reduced levels fatigue (as measured by scores on the fatigue subscale of the FACT-F) after 12 weeks compared to baseline.

Hypothesis 2: Participants using the Untire app intervention will show improved QoL (as measured by scores on the FACT-F) after 12 weeks compared to baseline.

Method and Design

Design

A between groups study design will be used to evaluate the acceptability and preliminary efficacy of the current version compared to the new version of the Untire mHealth intervention in TYA and adults with cancer related fatigue.

Participants

Participants will be recruited through the following channels:

- NHS Cancer Treatment centres within the South West of England.
- Charities and third sector organisations: Youth Cancer Trust, Cancer Support UK, Macmillan, Shine.
- Social media: support groups/ networks on Facebook and Instagram: Cancer Awareness for Teens and Twenties (CATTs).

Inclusion criteria:	Exclusion criteria:
• Adult with cancer or cancer survivors (18 years and older).	• Participants < 18 years of age
• Self-reported current diagnosis or previous history of treatment for cancer (cancer survivor).	Non-English language speakers
• A moderate or severe level of fatigue as measured by items 1-3 of the Brief Fatigue Inventory (BFI). An average composite score of ≥4 will be considered to represent clinically meaningful fatigue (Mendoza et al.,1999).	• Participants with a diagnosis of and receiving treatment for severe psychological distress (e.g. major depression, psychotic disorder, anxiety disorder, or addiction).

• Access to a smart phone, tablet, or iPad (Apple or Android).	• Participants with a diagnosis of chronic fatigue syndrome, myalgic encephalomyelitis, or fibromyalgia. • Previous or current us of the Untire app

Sample size/power calculation

As this pilot study will primarily focus on acceptability of the intervention, and is exploratory in nature, a priori power analysis is not required. The number of participants recruited to the study within the recruitment window (December 2022-December 2023) will be analysed.

To address the secondary aim of the study, 22 participants would be required to complete the post intervention measure at T12 (FACT-F). This was calculated using an a priori power analysis (power = 0.8, α error prob = 0.05) using the Minimal Detectable Effect (MDE) for the FACT-F, as reported by Cella et al (2002) for detecting meaningful change over time. Previous research on mHealth apps have suggested that 60% of participants will be lost to follow up over the course of the 12-week intervention (Anguera et al., 2016). To account for this, we aim to recruit at least 55 participants per group (55 in the current version group, 55 in the new version group).

Intervention

Current version

The Untire app is a registered medical device which helps cancer patients and cancer survivors improve cancer-related fatigue (ICD10 code R53.83 Fatigue) and associated quality of life (Spahrkäs et al., 2020). The self-management app was launched in 2018 and is available on the Apple App store / Google Play store.

New version

The Untire app is currently under re-development and the new version of the app is due to be released in April 2023. The new app incorporates additional

personalisation and several updated themes. Full details of the Untire app can be found in the above publication or on https://tiredofcancerapp.com.

It will be recommended that participants use the app daily, but participants will receive instructions to use the app at least once a week for 12 weeks. They can work through the app in any order and in their own time.

Outcomes / measures

Demographic / recruitment information

- Accrual rate of participants.
- Identification of most productive recruitment methods.
- Sample characteristics of those recruited.

Acceptability will be assessed through:

Acceptability E-scale (Tariman et al., 2011)

- Participants will complete this scale after 2 weeks of app use (T2), 4 weeks (T4), 6 weeks (T6) and T12 after completing the intervention. See Appendix 3 for full details.

Digital Working Alliance Inventory (D-WAI)

- Participants will complete an online version of the D-WAI at 2 weeks (T2), 4 weeks (T4), 6 weeks (T6) and T12. See Appendix 3 for full details.

Engagement will be assessed through:

- Retention and adherence throughout 12-week intervention.
- Non active users: participants who have not used the app for 14 consecutive days or fail to complete mid/ end point outcome measures) will be contacted by a researcher via email/phone to collect the reason for dropping out and to give brief feedback on the app.

- In app use: characteristics of app use by participants will also provide data on engagement. This will include the duration of app use (in days) and the degree of app use (amount of completed themes within the app).

Secondary outcome:
Preliminary efficacy of the Untire intervention In TYA cancer survivors will be assessed using the following outcome measure. To reduce the burden placed on participants, one combined outcome measure will be used for fatigue and QoL.

The Functional Assessment of Chronic Illness Therapy – Fatigue (FACT-F) (Yellen et al., 1997)

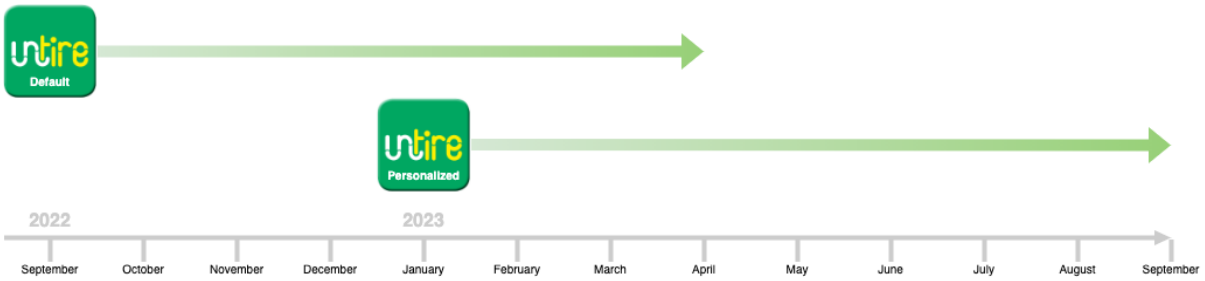
- Participants will complete this at baseline T0 and then again after 2 weeks(T2), 4 weeks (T4), 6 weeks (T6) and after completion of the intervention at week 12 (T12). See Appendix 3 for full details.

Recruitment strategy
Multiple recruitment strategies will be deployed to maximise study recruitment.

- NHS cancer services in the South West of England will be approached and an information sheet / email will be given out to clinicians to share with possible participants within their services.
- Charities and third sector organisations will be contacted with the aim of sharing the details of the study with their service users.
- Social media (Facebook, Instagram) will be used to reach out to support networks to publicise the study with the hopes of reaching cancer survivors who may have left NHS services.

To maximise the recruitment window for the study to a staggered recruitment method will be used with participants first being allocated to the current version of the app. When the new version is available, recruitment will run in parallel until the required number of participants is reached or the recruitment window closes. Quota sampling may be used to ensure an adequate number of participants in each age category

(TYAs 18-30, Adults 30+) to be able to stratify outcomes by age. The diagram below outlines our recruitment timeline.



Procedure

Recruitment and consent to screen	Potential participants will be directed to the QuestionPro study webpage via leaflet/email/social media page where they be able to read a study information sheet and then invited to give initial digital consent to be screened. They will then be asked screening questions to determine eligibility. These will include: • Date of birth (to ascertain age) • Current diagnosis or previous history of treatment for cancer (Y/N) • Consider themselves fatigued (Y/N) • Currently receiving help for fatigue (Y/N) • Access to a smart phone or tablet for the duration of the intervention (Y/N) • Previous or current us of the Untire app (Y/N) • If they can be contacted (email / text / phone) by a member of the research team throughout the study period. This will be to provide feedback on the app and assess its acceptability. • **Potential participants will also be asked if they are happy to be contacted about taking part in a related project. Contact details will not be shared outside of**

	research team and declining this will not prevent participation in the current study).
Consent to participate, Demographics and baseline outcome measures (T0)	Eligible participants will be asked to provide digital consent to participate in this study before providing brief demographic information. This will include: • Gender • Education level (years in) • Cancer type • Cancer treatment received • Cancer statement (undergoing treatment / no longer undergoing treatment) • Motivation to manage fatigue. (10-point Likert scale) • Motivation to work with an app. (10-point Likert scale) They will also complete the FACT-F at baseline (T0).
App access	Participants will then be emailed a link to access a version of the Untire app (current or new version). Access will be free for 12 weeks. They will be allowed to work through the app at their own pace and instructed to access the app at least once a week for the 12-week study period.
Outcome measures and drop out (T2-T6)	At each time point, 2 weeks (T2), 4 weeks (T4), 6 weeks (T6) and 12 weeks (T12) participants will be sent an email instructing them to complete the FACT-F, Acceptability E-scale, and Digital Working Alliance Inventory (via QuestionPro). Reminders will also be sent after one week if they have not yet been completed. If a participant does not use the app for 5 days, then an automated push notification is sent to them. If a participant does not use the app at least once in a 14-day period, then they will be considered to be 'nonactive users'. In this instance, and if they have previously consented to be contacted, a member of the research team will contact them to determine the reason for them no longer using the app (follow up interview).

Completion / acceptability (T12)	Participants who have completed 12 weeks of the Untire intervention will be invited to complete an additional feedback questionnaire.
Participant incentive	Participants who complete the 12-week intervention or those who take part in a follow up interview will be entered into a prize draw and have the chance to win a £50 amazon voucher (6 available). Dropping out of the study early will not exclude participants for entering the draw if they have provided feedback on using the Untire app.

End of the study

The end of this study will be defined by when the last participant finishes using the app, either by completing the full 12 weeks of app use (and provide feedback) or when they decided to stop using the app (drop out of the study). The Research Ethics Committee (REC) will be notified of the end of the study within 90 days.

Data collection, management, and analysis

Data collection methods

All study questions and outcome measures will be digitised and presented to participants using a web-based survey platform (QuestionPro). Participants who clicked on the study link will be brought to the study webpage via QuestionPro. Additional outcome measures will be emailed to participants unless another method is specified. Data on participant's app use is automatically logged and stored in a data log.

Data analysis

Descriptive statistics (means and standard deviation) will be used to summarise demographic and baseline outcome measure data across all participants. Assumptions of linearity, homogeneity of variance as well as the normal distribution of outcome measure data will be tested.

To assess acceptability of the app, a χ^2 test will be used to assess whether participant's Acceptability E-scale scores met the pre-established cut off for acceptability (≥24, Tariman et al., 2011).

A Linear mixed model will be used with the 5 repeated measures (T0,T2,T4,T6,T12) and the two group (current version and new version) to analyse acceptability outcomes (Acceptability e-scale and DWAI scores).

To assess preliminary effectiveness of the app (reducing fatigue, improving QoL), FACT-F scores will be analysed across the five time points (repeated measures) using a linear mixed model.

Linear regression will be used to look for an association between therapeutic alliance (as measured by D-WAI scores) and user engagement (duration of app use) and fatigue outcomes.
It is hoped that a subgroup analysis will be conducted to identify difference in acceptance and fatigue outcomes between younger (18-30) and older (30+) app users.

Dissemination

The journal of Psycho-Oncology will be targeted for publication of this study. This journal focuses on the psychological, social, and behavioural dimensions of cancer, and was the journal that published the original Untire RCT. Findings will also be shared with Tired of Cancer, with the plan that study results will help further develop the Untire app.
We also aim to present our findings (through a poster or short video) on social media, to the NHS services involved, and the TYA cancer survivor representatives who assisted with the study providing valuable feedback.

Clinical implications of this study

It is hoped that the results from this study will demonstrate whether the new Untire app is an acceptable intervention for adults with cancer related fatigue. This, along with any preliminary findings in terms of effectiveness, will hopefully give justification

to clinicians that the Untire app is a viable self-management app which can compliment other treatment options. Findings will hopefully inform further refinements of the app to engage a younger audience and stimulate larger trials in the use of the Untire app in the future.

PPE involvement

The aim is to recruit at least two service users from the TYA cancer service in Bristol University Hospital to join our research team, and potentially the Patient and public Engagement (PPE) panel for the University of Bath. We intend to invite this representative to a pre-study focus group to gain their feedback on the Untire app and any considerations for engaging TYA with cancer or survivors in the 12-week intervention. We also intend for our PPE representatives to consult on all study materials and review consent forms / information sheets ensuring they are suitable for the client group. They will be invited to our monthly cancer research meetings between University of Bath and UHBW to provide consultation on this project and others like it. PPE representatives will be paid for their time. We anticipate each PPE will spend 2-3 hours consulting on the project.

Ethical considerations/ issues

The study will require both ethical approval from the University of Bath Research Ethic Committee and NHS research ethics approval.

Participants will be asked to read and sign an online consent form before accessing the Untire app. Participation will be entirely voluntary, and they can withdraw or stop using the app at any time. Choosing to withdraw will not impact the care they receive from services. Participants will be contacted if they drop out but only if they have given their prior consent to do so. They will be allowed to continue using the app if they wish.

There are no anticipated risks for participants involved in this study. Careful consideration will be made to minimise the burden placed on participants. The number of questions will be kept low and relatively short outcome measures will be used. After the study period is completed (12 weeks of app use), participants in the

current app group will be given access to the updated version of the app for them to use for 12 weeks if they wish. This is so no participant in this study will miss out on any additional benefits provided by the updated version of the app.

Potential problems and Contingency planning

Recruitment and retention may be particularly difficult with the TYA client group. As such, there is a plan to use a variety of recruitment methods to maximise participant numbers. We hope to also connect with the national network of TYA cancer services to promote this study nationally.

Retention rates are an issue with mHealth interventions and are likely to be an issue in this study. Participants will be followed up with more closely and reasons for drop out will provide important information. It is hoped that it might lead to higher rates of study adherence.

All aspects of this study, including data collection, will be done remotely. Participants will use their own devices and outcome measures will be collected using a web-based platform. It is hoped that the study be able to continue even if there are future national lockdowns.

Technical difficulties with the app are another possible challenge. We aim to work closely with the Untire app team, which will allow us to report back any technical difficulties if they arise.

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Appendix

Appendix 1

Trainee Name:	Emil Vuillermoz
Cohort:	2021
Clinical tutor:	Dr Pamela Jacobsen

BUDGETED AMOUNTS:	£	500.00	
Participant payments	£	390.00	£90 for PPE representatives for consultation on project. 2-3 (hours at £15 per hour) x 2 PPEs £300 for Amazon vouchers (6x£50) for participant who complete study / complete feedback. Participants will be randomly selected for vouchers
Photocopying	£	-	
Postage	£	-	
Stationery	£	-	
Copies of measures/tests	£	-	
Miscellaneous*	£	110.00	

£	**500.00**

**Please detail any miscellaneous costs below:*
£30 donations to charities for their help with study recruitment (approx. amount).
£80 for research mobile phone, pay as you go sim and credit for calls / texts to participants

Appendix 2

Outcome measures

Brief Fatigue Inventory (BFI, Mendoza et al., 1999)

Items 1-3 will be used for eligibility screening.

1. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your fatigue right NOW.

0	1	2	3	4	5	6	7	8	9	10
No fatigue										As bad as you can imagine

2. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your USUAL level of fatigue during past 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No fatigue										As bad as you can imagine

3. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your WORST level of fatigue during past 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No fatigued										As bad as you can imagine

Acceptability E-scale (Tariman et al., 2011)

This is a six-item scale measuring how easy and enjoyable the app is to use, how understandable were the questions, how helpful was completing the intervention, whether the amount of time to complete the program was acceptable, and overall satisfaction with the program. This is a valid and reliable measure which has previously been used to evaluate patient perceptions of e-health interventions in an oncology setting (Underhill et al., 2017).

Responses are on a simple 5-point numerical scale; 1 indicates a negative and 5 indicates a positive evaluation. Scores range can range from 6-30. The scale will be adapted with the appropriate wording for this study.

Acceptability E-Scale

Now we would like to ask you about your thoughts on using the Untire app.

1. How easy is / was the Untire app for you to use?

1	2	3	4	5
Very difficult				Very easy

2. How understandable are / were the questions?

1	2	3	4	5
Difficult to understand				Easy to understand

3. How much are you / did you enjoying using the Untire app?

1	2	3	4	5
Not at all				Very much

4. How helpful is / was the Untire app in managing your symptoms and quality of life?

1	2	3	4	5

Very unhelpful	Very helpful

5. Is / was the amount of time it took to complete the Untire intervention acceptable?

1	2	3	4	5
Very unacceptable				Very acceptable

6.How would you rate your overall satisfaction with the Untire app?

1	2	3	4	5
Very dissatisfied				Very satisfied

Sections in grey will be changed dependant on which time point the participant is at (T4/8/T12). This scale will be digitised and presented using QuestionPro.

Digital Working Alliance Inventory (D-WAI)

The DWAI (Henson et al., 2019) is a brief questionnaire used to assess digital working alliance. The 6-items are based on the successful validation of a short form of the Working Alliance Inventory (WAI-SR, Goldberg et al., 2021) comprising of the same core factors of Goals, tasks, and bond. Goldberg et al. (2021) reported that the DWAI reported adequate internal consistency and test-retest reliability. It is a 6-item self-report questionnaire with responses rated on a seven-point Likert scale, ranging from 1 (strongly disagree) to 7 (Strongly agree).

1. I trust the app to guide me towards my personal goals.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

2. I believe the app tasks will help me to address my problems.

1	2	3	4	5	6	7

Strongly disagree						Strongly agree

3. The app encourages me to accomplish tasks and make progress.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

4. I agree that the tasks within the app are important for my goals.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

5. The app is easy to use and operate.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

6. The app supports me to overcome challenges.

1	2	3	4	5	6	7
Strongly disagree						Strongly agree

The Functional Assessment of Chronic Illness Therapy – Fatigue (FACT-F) (Yellen et al., 1997)

This is a 40-item questionnaire which comprised of the 27-item Functional Assessment of Chronic Illness Therapy – General (FACT-G) designed to measure four domains of Health related QOL in cancer patients: Physical, social, emotional, and functional well-being. The FACT-F included an additional 13-item subscale that can be used as an independent measure of fatigue and its impact.

The FACT-G (core subscales) has been shown to have good test-retest reliability (r=0.87) and excellent internal consistency (alphas = 0.95) on both initial and retest administrations (Yellen et al., 1997). The fatigue subscale has independently demonstrated good test-retest reliability (r=0.90) and internal consistency (alphas = 0.93 and 0.95) on initial and test-retest administrations (Yellen et al., 1997).

Responses are measured on a five-point Likert scale. The measure takes 10-15 minutes to complete.

FACIT-F (Version 4)

Below is a list of statements that other people with your illness have said are important. **Please circle or mark one number per line to indicate your response as it applies to the past 7 days.**

	PHYSICAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box* ☐ *and go to the next section.*					
GS7	I am satisfied with my sex life	0	1	2	3	4

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	EMOTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	ADDITIONAL CONCERNS	Not at all	A little bit	Some-what	Quite a bit	Very much
HI7	I feel fatigued	0	1	2	3	4
HI12	I feel weak all over	0	1	2	3	4
An1	I feel listless ("washed out")	0	1	2	3	4
An2	I feel tired	0	1	2	3	4
An3	I have trouble starting things because I am tired	0	1	2	3	4
An4	I have trouble finishing things because I am tired	0	1	2	3	4
An5	I have energy	0	1	2	3	4
An7	I am able to do my usual activities	0	1	2	3	4
An8	I need to sleep during the day	0	1	2	3	4
An12	I am too tired to eat	0	1	2	3	4
An14	I need help doing my usual activities	0	1	2	3	4
An15	I am frustrated by being too tired to do the things I want to do	0	1	2	3	4
An16	I have to limit my social activity because I am tired	0	1	2	3	4

Appendix 3

Study timeline