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The effectiveness of online Acceptance and Commitment Therapy (ACT) versus a waiting list control condition on pain interference and quality of life in adults with chronic pain and multimorbidity: Protocol for a randomised controlled trial

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Abstract:

Introduction*:* Multimorbidity refers to the presence of two or more chronic health conditions within one person, where no one condition is primary. Research suggests that multimorbidity is highly correlated with chronic pain, which is pain lasting longer than 3 months. Psychotherapeutic interventions for people living with chronic illness have resulted in reduced symptom reporting and improved psychological well-being. There is a dearth of research, however, using online psychotherapy for people living with multimorbidity where chronic pain is a central condition. This study will compare the clinical-effectiveness of an online Acceptance and Commitment Therapy (ACT) intervention with a waitlist control condition in terms of improving health related quality of life (HRQoL) and reducing levels of pain interference in people with chronic pain and at least one other condition.

Methods and Analysis: 192 adult participants with non-malignant pain that persists for at least three months and at least one other medically diagnosed condition will be randomised to one of two study conditions. The experimental group will undergo an 8-session internet-delivered ACT-program over an 8-week period. A wait-list group will be offered the ACT intervention after the 3-month follow-up period. Health related quality of life and pain interference will act as the primary outcomes. Data will be analysed using a linear mixed model and adjusted to account for demographic and clinical variables as necessary. A Study Within a Trial (SWAT) will be incorporated to examine the effect on recruitment and retention of showing participants an animated educational video.

Ethics and dissemination: Ethical approval has been granted by the Research Ethics Committee of the National University of Ireland, Galway. Dissemination of results will be via peer reviewed journal articles and conference presentations.

Strengths and limitations of this study:

The study aims to deliver an online ACT intervention for people with chronic pain and at least one other health condition. Interventions for people with chronic health problems tend to focus on one condition, and do not account for other symptoms or conditions a person may have. Research has shown that people with chronic pain typically have at least one other chronic health condition. In fact, chronic pain is one of the most common conditions to be found in multimorbid disease combinations. To our knowledge this is the first randomised control trial to target the improvement of important health outcomes for people with chronic pain and multimorbidity. As such, the aims of this study are novel and would provide useful information for both the applied and research communities, as well as potentially reducing pain interference and improving HRQoL for patients.

The study methodology and design are based on previous research so we do not anticipate many limitations. However, this is the first study to adopt ACT for multimorbidity and chronic pain and there may be issues with the adaptation. That said, the adaptation for the current study was supervised by a clinical psychologist who specialises in ACT and chronic pain and we do not envisage any issues, moreover, the efficacy of the program as an intervention, is an empirical question and one which the study aims to answer.

INTRODUCTION

Background and Rationale

Multimorbidity

Multimorbidity is defined "as the co-existence of two or more chronic conditions, where one is not necessarily more central than the others" (Boyd & Fortin, [1] 2010, p.453). Traditionally, medicine has taken a single disease approach to the management of chronic conditions.[1]. However, as Boyd and Fortin amongst others [2,3] suggest, such an approach to disease management is becoming increasingly untenable as greater numbers of people present with multiple conditions In fact, as Violan et al.[4] highlight, multimorbidity is now considered the norm rather than exception in primary care patients and some, including Salisbury,[3] acknowledge that managing multimorbidity is the most important task facing health services in developed countries.

Risk factors & Prevalence

Prevalence estimates of multimorbidity vary from country to country. Recent research in Australia suggests that 25.5% of the population live with multimorbidity, [5] the prevalence of multimorbidity in Scotland is reported to be 23.2 %,[2] while in Ireland 45.3 % of the population are reported to have multimorbidity.[6] Indeed, prevalence rates of multimorbidity vary between subsets of different populations and are often found to be higher for those people who attend medical services. For example, Fortin and colleagues found that 90% patients in primary care in Canada had more than one condition,[7] while in an Irish study, 66.2% of patients in primary care had multimorbidity.[8]

Although prevalence rates vary across populations and groups, it is clear that increasing numbers of people are developing multimorbidity. The rise in multimorbidity is due in part to improving technology, advancements in medicine, and better health policies.[9] In terms of risk factors, research has shown that the most reliable predictor of multimorbidity is age. For example, one study found that the prevalence of two or more co-existing medical conditions in 18- to 44-year, 45- to 64-year, and 65-year and older age-groups were, 68%, 95%, and 99%, respectively.[7] However, while multimorbidity is positively correlated with age, it must be noted that it is not only the burden of older generations, as Agborsangaya et al [10] found that 70.2 % of their sample under the age of 65 live with multimorbidity. Other risk factors, including socioeconomic status, adverse childhood experiences,[6] poor physical activity, and risky health behaviours (e.g., smoking) are also important contributors to multimorbidity.[3]

Impact

Living with multiple chronic conditions has debilitating physical, psychological, social and financial consequences for a person and their family. Specifically, multimorbidity increases the risk of engagement with healthcare providers (i.e., hospitalisations), loss of physical functioning, depression, anxiety, polypharmacy, and ultimately has an impact on a person's health related quality of life (HRQoL).[11,12] HRQoL is a health outcome measure, which is an indicator of an individual's overall well-being, and it is typically used to assess the effectiveness of interventions; it is therefore a predictor of treatment success and it is increasingly used to support "allocation decisions in the health care sector".[13] Research has shown unequivocally that chronic disease has a negative impact on HRQoL; [11,12] and it

has been found that having multiple chronic conditions has an exponential impact on a person's well-being.[13] Therefore, there is an interaction effect rather than a cumulative effect of multimorbid chronic conditions on HRQoL.[13] Due to the increasing prevalence of multimorbidity and the burden of living longer with these conditions, the aim of improving HRQoL for people with multimorbidity has now become central to the focus of health practitioners.[14]

Chronic Pain and Multimorbidity

Chronic pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described by the patient in terms of such damage" that persists for a period in excess of 3 months. [15] Chronic pain is a major public health problem that can have debilitating physical, emotional, psychological, and financial consequences for those individuals living with it.[16–18] Prevalence estimates for chronic pain vary [12–14,19,20], however one recent study found that 35.5% of the Irish population were living with chronic pain. [14]

Chronic pain is highly correlated with multimorbidity, and is consistently identified as one of the most common conditions in those identified as having multimorbidity.[5] For example, in one Canadian study that examined the prevalence of disease-combinations, sixteen common disease pairs were identified, with chronic pain appearing in six of the combinations. Further, from the five most common disease triads identified in the same study, chronic pain was involved in three of these combinations.[5] Boyd and Fortin [1] noted that if a person had one chronic condition they were quite likely to also have another. Considering that over a third of the Irish population are reported to have chronic pain, and chronic pain is highly correlated with multimorbidity, it is important that research accounts for the relationship between the two.

Psychological Interventions for multimorbidity and chronic pain

Cognitive Behavioural Therapy (CBT) is frequently used when a psychological treatment is required as part of a multidisciplinary rehabilitative process for people with chronic conditions and has been employed widely, for example, with people who live with chronic pain.[8–13] Although CBT-based treatments are effective with many disorders, this is not the case for all conditions.[21] As a result, research has investigated the effects of other psychotherapeutic approaches. [22–24] Recently, Acceptance and Commitment Therapy (ACT) has gained considerable empirical support for improving HRQoL in people living with chronic conditions. [23,24]

Whereas CBT focuses on the reduction of symptom-related distress, ACT promotes 'psychological flexibility' (i.e., the ability to separate oneself from one's condition and its associated symptoms). From the perspective of ACT, increasing psychological flexibility for a person with a chronic condition is a stepped process that emerges through (a) the active recognition of symptoms and their associated thoughts, which (b) allows for the acceptance of the symptoms, and (c) enables the person to differentiate themselves as a separate entity from their condition. This latter process, known as psychological defusion, allows a person to be aware and accepting of aversive thoughts and feelings, identify what their values are, and then partake in committed action to achieve those values.[25] ACT has been successfully deployed as a psychological intervention to improve functioning and quality of life for people living with numerous chronic conditions, including depression,[26] tinnitus,[27] diabetes,[28] cancer,[29] post-traumatic stress,[30] and chronic pain.[31]

ACT Online

Traditionally, psychotherapeutic interventions, such as ACT, have been administered face-to-face when a client meets with a therapist. This face-to-face approach, however, is subject to numerous constraints including direct and indirect costs, high labour demands, long waiting lists, mobility and accessibility issues, and shortages in appropriately trained health care professionals.[32,33] The provision of one-to-one therapy is therefore not feasible for wide scale health interventions. To negate these limitations, researchers have begun to administer psychological interventions online. [21,34–39] These programs provide standardised psychological treatment over the internet and are promising in their cost-effectiveness and accessibility, as results have shown them to be efficacious.[39] For example, one recent randomised controlled trial examined the effectiveness of an online ACT intervention for people living with chronic pain.[40] Participants were randomly assigned to an online treatment group for 7 weeks or to a control group that participated in a moderated online discussion forum. Results showed that participants in the experimental group demonstrated increased activity engagement and willingness to experience pain and reductions were found on measures of pain-related distress, anxiety and depression. Furthermore, these improvements were maintained at a six-month follow-up.[40]

Objectives

There is a large body of research that supports the use of psychotherapy and internet-delivered psychotherapy for people living with chronic pain. However, there is a dearth of research that attempts to improve HRQoL for people living with multimorbidity using any form of intervention, and there is no research that specifically examines the delivery of any form of psychotherapy to improve HRQoL and reduce pain interference for people living with multimorbidity where chronic pain is a feature. Moreover, ACT interventions for people living with chronic illnesses tend to be symptom-specific and target a particular disease; however, it is clear that a large proportion of people with one chronic illness live with one or more additional chronic conditions. In light of these issues, the proposed randomised control trial will examine the clinical effectiveness of an internet-delivered ACT intervention for people living with multimorbidity featuring chronic pain. It is hypothesised that people in the ACT treatment group will report significant improvements in pain interference, HRQoL, physical functioning, emotional functioning and rating of overall improvement, relative to a waitlist control group.

Trial design

The design is a single-blind randomised controlled trial comparing the effect of an internet-delivered ACT intervention with a waiting list control condition on HRQoL and pain interference (primary outcomes) for people with multimorbidity where chronic pain is one of their conditions. This protocol will be reported in accordance with the SPIRIT guidelines (Supplementary File 1). [41]

METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

Study setting

The intervention is delivered in an online format and therefore participants can complete the intervention in their own homes. Study coordination and analysis will occur in the Centre for Pain Research at the National University of Ireland, Galway.

Eligibility Criteria

Inclusion criteria: aged at least 18 years; the presence of two or more chronic conditions (including chronic pain) reported by the patient as having been diagnosed by a doctor; resident of the Republic of Ireland; access to a computer/tablet and the internet; not currently undergoing any form of psychological treatment; sufficient competence in the English language (as determined by the participant) to complete the various elements of the study; informed consent is required. Exclusion criteria: severe cognitive impairment or psychiatric disorder that would interfere with the person's capacity to complete the study.

Patient Involvement

This study is based on a previous programme conducted at the Centre for Pain Research at NUI Galway [33]. Participant feedback (priorities, experiences and preferences), from that trial, and the pilot for this RCT were incorporated into the design of the intervention and the data collection. Patients will not be formally involved in recruitment for the study, but patient advocacy groups will be involved in promoting the study. We will communicate the results to participants by email when they are available.

Interventions

Experimental Group

The treatment protocol is almost identical to that used in a previous study by Hayes et al. examining the clinical and cost effectiveness of an internet-delivered ACT intervention for people living with chronic pain.[33] The intervention was derived from an ACT treatment manual specifically devised for people with chronic pain [42] and adapted for online dissemination. Hayes et al. utilised other resources [43–45] and a team of healthcare professionals, including physiotherapists and clinical psychologists who specialise in chronic conditions and ACT treatments to revise the material so that it was modified accordingly and was suitable for online delivery. [33] Thus, the online ACT treatment designed by Hayes et al. is a robust adaptation and has been adopted for the purposes of the current research.

Appropriate changes to the content were made, so that the ACT programme designed by Hayes et al. can be used in the current study for people with multiple conditions rather than for chronic pain only. The core concepts, homework, metaphors, and mindfulness exercises, have for the most part, not been altered in any way. The only amendments necessary to the Hayes et al. ACT treatment program were to alter the content that referred to symptoms of chronic pain specifically to instead refer to living with multimorbidity.

The experimental treatment will consist of eight sessions over an eight week period and will be hosted on the NUI Galway, Centre for Pain Research Website. The program will be delivered via an interactive online platform, and will consist of information, homework

assignments, relevant metaphors and mindfulness exercises. The focus of this treatment protocol is on increasing psychological flexibility by developing acceptance, present-focused awareness and engagement in values-based action. An overview of the treatment is provided in Table 1.

Over the course of the trial, participants in the experimental group will be prompted to via a weekly email reminder to complete each session. Adherence to the intervention will be monitored. If a participant wishes to discontinue their involvement they will be withdrawn from the intervention and this will be reported as attrition.

Wait-list control group

The waitlist control group will be offered the opportunity to use the online ACT intervention following the 3-month follow-up assessment.

Table 1: Overview of the internet-delivered ACT intervention program (similar to protocol used in Hayes et al., 2014)[33]

Week	Session	Summary of content
1	Session 1	• Introduction to the ACT program and program overview • Review of treatment history and evaluate it in terms of how it has worked relative to the participant's goals and expectations • Review the interactions between thoughts, feelings and function, which often serve to make each other worse (e.g. become a "vicious cycle") • Introduce the idea that change is possible - not based on symptom reduction but on aiming to alter function • Introduction to mindfulness technique • Homework assignment: check in with self daily and focus on activities.
2	Session 2	• Introduction to the concept of acceptance and how one's experience of their symptoms from their various conditions may limit participation in valued activities • Explanation of values • Mindfulness explanation & debrief • Homework assignment: Mindfulness practice daily
3	Session 3	• Identification & clarification of values • Assessment and rating of values • Discrepancy between values and current function • Leave on a stream mindfulness exercise • Mindfulness debrief • Homework assignment: Mindfulness practice daily
4	Session 4	• Barriers to pursuing values • Overcoming barriers • Swamp metaphor - exercise exploring the possibility for values-based action even with aversive experiences. Discussion on the concept of willingness and unwillingness to have discomfort • Body scan mindfulness exercise

5	Session 5	• Goal setting exercise in line with 3 chosen values • Discussion on fluctuating levels of high and low functioning and benefits of activity pacing in order to achieve a more consistent level of activity from day to day. • Homework assignment: Record performance over the next week regarding carrying out specific actions and pacing of activities and practice mindfulness every day.
6	Session 6	• "Tricks of the mind" exercises to raise awareness of language-based influences on function • Cognitive defusion exercises - Finding a place to sit metaphor, Get off your Buts exercise, Milk exercise, Passengers on a bus Exercise and "buying" thoughts. • Homework assignment: practice mindfulness and cognitive de-fusion techniques daily
7	Session 7	• Planning and action • Willingness and Committing to action • Mindful Walking exercise • Homework assignment: commit yourself to action
8	Session 8	• Emphasis on commitment to actions and values even when barriers exist and future planning - this is a "lifelong assignment" • Preparation for relapses and setbacks • End of programme • Recap on topics covered throughout the programme

Outcome measures

Demographic and clinical information

Participants will be asked to provide details regarding age, gender, highest educational attainment, occupational status and relationship status as well as number and type of chronic conditions and duration of their conditions (including BMI) using a multimorbidity checklist. Some details about previous and current medical and alternative treatment will also be collected.

Primary outcome measures

Brief Pain Inventory (BPI) - Short form

The BPI-Short form [46] is a 9-item instrument that measures the interference and severity of a person's pain and the impact of their pain on their daily functioning, and is a standardised and widely used measurement tool for assessing chronic pain. The first eight items ask the person to provide demographic information, medicinal measures to alleviate pain symptoms, to identify locations of pain, and to rate their pain severity from 1-10 (10 being the most severe pain) on a visual analogue scale over the past 24 hours. Item 9 is further divided into seven sub-items, examining interference with function. The sub-items can then be grouped into those assessing physical functioning (i.e., general activity, walking ability, and working ability), those assessing psychological functioning (i.e., mood, relations with other people, and enjoyment of life) and one item investigating the extent to which pain affects sleep. The

BPI has demonstrated good construct validity, adequate internal consistency,[47] Cronbach's alpha, α= 0.88 and acceptable test-retest reliability.[48]

12 Item Short Form Survey (SF-12)

The SF-12 is a standardised instrument used as a measure of HRQoL.[49] A shortened version of the SF-36, it reduces participant burden while still providing sub-scale scores across eight health domains (general health, physical functioning, emotional role limitation, physical role limitation, mental health, bodily pain, vitality and social functioning). It also produces two summary scores, a Mental Component Summary (MCS) and a Physical Component Summary (PCS) of HRQoL [50] with lower scores on these scales representing lower quality of life.

Secondary outcome measures

Patient Global Impression of Change scale (PGIC)

The PGIC is a subjective indicator of the extent to which a treatment has led to a change in symptoms. It has been recommended for use with chronic conditions and endorsed by IMMPACT as a core outcome measure in CP trials.[51] The PGIC is a single-item with a seven point scale, where response options are 'very much improved', 'much improved', "'minimally improved', 'no change', 'minimally worse', 'much worse', and 'very much worse'. The proportion of each of the seven response options in both the control and treatment group will be analysed and reported.

The Acceptance and Action Questionnaire II (AAQ-II)

The original AAQ [52] has been used extensively with chronic conditions[29,53,54] and the AAQ-II [51] is widely used in measuring psychological inflexibility and experiential avoidance. The AAQ-II is a seven item questionnaire, in which participants rate their responses to each item on a 1-7 scale in terms of how likely they are to accept or avoid aversive thoughts and feelings (1 = 'never true' and 7 = 'always true'). The higher the participant scores overall, the greater the level of psychological flexibility. The AAQ-II has good content, construct, convergent and predictive validity [49] and satisfactory reliability.[55]

Chronic Pain Acceptance Questionnaire-8 (CPAQ-8)

The CPAQ-8 [56] the shortened version of the Chronic Pain Acceptance Questionnaire (CPAQ) [53] is an eight item questionnaire and is rated on a scale from 0 to 6 (0= 'never true' and 6= 'always true'). The questionnaire contains two subscales; pain willingness and activity engagement, which are summed to indicate overall acceptance of pain. The CPAQ-8 has been validated in various populations [57,58], has adequate to good reliability and consistency with Cronbach's alpha coefficients ranging from 0.69 to 0.86, and good test-retest reliability with an overall score correlation of 0.81.[59]

Multimorbidity Illness Perceptions Scale (MULTiPleS)

The Multimorbidity Illness Perceptions Scale (MULTIPleS) [60] was developed to measure patient illness perceptions in the context of MM. Illness perceptions are a person's persistent

thoughts and feelings about their disease. The MULTIPleS is a 22 item questionnaire. The respondent indicates their level of agreement with each item on a Likert scale; the first 16 item scores range from 0 to 3, where '0' indicates that a person 'strongly disagrees' with an item and '3' indicates that a person 'strongly agrees' with an item, and the remaining 6 items range from 0 to 5. Overall, the 22 items comprise five subscales; emotional representation, treatment burden, prioritising conditions, causal link, and activity limitations. The MULTIPleS is relatively new - Gibbons et al. [60] found that the scale provided a good fit to the Rasch model and demonstrated evidence of reliability and validity for each of the subscales.

Patient Health Questionnaire (PHQ-9)

The PHQ-9 is a widely used measure of depression.[61] Items relate to the criteria for depression in the DSM V, and are scored on a 4 point Likert scale, ranging from 0 ("not at all") to 3 ("nearly every day"). Higher scores indicate the person meets more of the symptom criteria; scores above 10 indicates moderate depression, and scores above 15 indicates a clinical case of moderately severe depression. It has been used and validated with chronic condition populations.[17]

GAD-7

The GAD-7 a validated and standardised measure, will be used to measure anxiety.[62] The seven item questionnaire presents items relating to how often over the past couple of weeks a person has felt bothered by the seven DSM V criteria symptoms of generalized anxiety disorder. Items are scored on 4 point Likert scales ranging from 0 "not at all" to 3 "nearly every day". A higher overall total score indicates greater symptom severity.

Client Services Receipt Inventory (CSRI)

The CSRI [63] has been used widely in research examining the cost of CP [18,64,65] and has been shown to be a valid measure of frequency of health service use.[66] Medication and health service use will be measured at baseline, post-treatment and follow-up, using a modified version of the CSRI. As medication use will most likely vary throughout the trial, change in medication use (including prescribed and over-the-counter medications) will be examined in post-treatment analysis.

Study timeline

Interested participants will complete a screening questionnaire that will determine whether they satisfy the inclusion criteria, they will then complete another questionnaire that will capture demographic information and baseline data. Potential participants will receive a scripted phone call involving a further explanation and an opportunity to ask questions. They will then be randomised online to either the intervention or control group. Both groups will be asked to complete questionnaires at post intervention (8 weeks) and at follow up (3 months). Participants in the wait list control will then receive access to the program. The process is outlined in the schematic diagram of participant flow (Supplementary File 2). As a point of note, a Study Within a Trial will be conducted examining the effect of a short video on retention.

Sample size

In line with statistical convention and Cohen's recommendations,[67] a sample size of 77 per group (total = 154) will have the desired power of .8, with a .025 alpha level to detect a medium effect size (d = .50 to .79) and both a significant clinical (i.e., 5 point difference or one-half its standard deviation)[68] and statistical difference in HRQoL between the experimental and control groups based on a two-tailed independent samples t-test. In accordance with the results of a previous study using online ACT for chronic pain [40] , using an alpha value of 0.025 and a desired power of 0.8, a total of 124 participants (62 per arm) are required to detect a medium difference in pain interference between the experimental and control groups. When calculating both sample sizes, an alpha value of 0.025 was used to account for multiple primary outcomes.

In order to detect both primary outcomes, the larger sample of 154, will be used. A recent study protocol with a similar design to the current study reported an expected 20% participant attrition rate between Time 1 and Time 3.[40] To take account of this potential attrition rate, 192 participants will be recruited in the current study (96 per arm).

Recruitment

Participants will be recruited through advertisements about the study across a variety of contexts. Advertising will be done through websites that provide information on various chronic conditions typically found in an Irish context. Advertisements will also be posted in any relevant publications, forums, or discussion boards where potentially interested parties are identified and through social media and the website of the Centre for Pain Research at NUI Galway. Furthermore, information will be given to relevant healthcare professionals, groups and communities to disseminate about the trial as they see fit. Interested people will be directed to a website (Centre for Pain Research, at NUI Galway) where the trial is based, and encouraged to read additional information about the trial before they sign up. Potential participants will be told they can contact the research team should they have any questions or wish to clarify any information before they apply to participate.

METHODS: ASSIGNMENT OF INTERVENTIONS

Allocation

When a participant agrees to take part in the trial they will be randomly assigned to the intervention or waiting list control group using random permuted blocks to ensure groups are balanced. Randomisation will be performed using a custom-written script, administered from a password-secured server. As such, researchers do not hold influence in the allocation process.

Blinding

For initial analysis, the data analyst will be blinded to group allocation; however, because the trial delivers a psychological intervention it is not possible to blind the participants to the groups they are in.

METHODS: DATA COLLECTION, MANAGEMENT, AND ANALYSIS

Data Collection Methods

All outcome measures administered at pre-intervention, post-intervention and at 3-month follow up are self-report and will be conducted online using the survey software Limesurvey (www.limesurvey.com). The participant attrition rate and any adverse events that may occur for the participants while they complete the intervention will also be recorded. Unless participants formally discontinue the study, attempts will be made to collect outcome data.

Data Management

All study information will be collected online, using surveying software installed on a secure server managed by the research team at the Centre for Pain Research, School of Psychology. NUI Galway. The software and server are password protected and only two members (BMcG and LOC) of the team hold the password. Non-identifiable information will be exported from the surveying software as needed, and shared only with the research team on secure computers based within the Centre for Pain Research at NUI Galway.

Statistical Methods

Data will be analysed using the principles of intention-to-treat analysis. Date will be summarised by appropriate graphical (e.g., box plots, labelled scatter plots and case profile plots) and numerical methods (e.g., frequency counts, means, medians, standard deviations, and quartiles). The first primary outcome measure, the SF-12, produces scores on eight subscales and two summary scores, which are transformed into a 0-100 scale. As such, the data from the SF-12 will be treated as a continuous variable [68] and the data from this measure over time (e.g., baseline versus post-intervention versus 6-month follow-up) will be analysed using a linear mixed model and adjusted accordingly to account for demographic and clinical variables as necessary. The second primary outcome, pain interference, measured by the BPI short-form, is scored by calculating the mean of seven different interference items; walking, work, mood, enjoyment of life, relations with others, sleep, and general activity. The pain interference data is rated on a scale of 0-10 and will be treated as a continuous variable and analysed as above. The secondary outcome measures will be treated as continuous variables also and analysed in a similar fashion. However, the PGIC yields ordinal data and as such a non-linear method will be employed to analyse this information. Each hypothesis will be tested using a two-tailed analysis at $\alpha = 0.05$ level of significance and missing data will be treated using multiple imputation analysis. A Bonferroni adjustment will be applied to results in order to account for the presence of multiple outcomes. All analyses will be completed using SPSS version 22 [69] and Stata IC 13.[70]

METHODS: MONITORING

Data Monitoring

All study information will be collected online, using surveying software installed on a server managed by the research team. The software and server are password protected. Non-identifiable information will be exported from the surveying software as needed, and shared only with the research team.

Adverse events

Adverse events will be recorded. No harm is anticipated to arise from participating in this study. However, as with any psychotherapeutic intervention there is a slight chance that some content or their participation will cause distress to some participants. Participants will be made aware, should such an event arise, to contact a member of the research team who will refer them to appropriate support services. In addition, clinical staff within the Centre for Pain Research will be on hand to offer additional support if necessary.

ETHICS AND DISSEMINATION

Research ethics approval

Ethical approval has been granted by the National University of Ireland Galway Research Ethics Committee ref: ('NUI Galway Research Ethics Committee 16/JAN/01')

Protocol amendments

In the event that amendments are made to the protocol, the trial registration will be updated. This study is based on a previously run study, as such significant changes are not anticipated, in the event that changes occur they will be communicated to participants via email.

Consent

Consent will be obtained electronically prior to enrolling in the study (Supplementary File 3). In addition, a phone call will offer participants the chance to formally withdraw before allocation.

Confidentiality

All study-related information will be stored securely at the Centre for Pain Research, School of Psychology, NUI Galway, where the research is taking place. Electronic data will only be accessible to the research team and will be stored on secure computers that are password-protected.

Declaration of interests

The authors declare that they have no competing interests.

Access to data

Members of the research team will have access to the data during analysis. Anonymised participant level data and statistical code will also be available to researchers upon request.

Ancillary and post-trial care

Given the nature of the study, it is not anticipated that participants will experience adverse effects. In the event that this occurs, participants are encouraged to contact the research team for further advice.

Dissemination policy

The findings of the trial will be submitted for publication in peer-reviewed journals and will be disseminated through conference presentations.

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Protocol Version 1, 25/04/18

Author Contributions

BWS, LO'C, KB, SH are involved in the design, delivery and evaluation of the trial and also drafted the manuscript. KF, CPD, SO'H, LC, and JE were involved in the editing of the manuscript and will be involved in the evaluation of the trial. BMcG contributed to the design of the intervention, supervises the delivery and evaluation of the study, and contributed to editing the manuscript.

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Competing interests

The authors declare that they have no competing interests.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page No
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	24
Funding	4	Sources and types of financial, material, and other support	24
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 24
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-7
	6b	Explanation for choice of comparators	
Objectives	7	Specific objectives or hypotheses	7

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	8-10
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8-10
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10-12
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12-13 & Appendices
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	14
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	14
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	14
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	14
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	14
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	14
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15

Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	15
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	15
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	15
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	16
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	16
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	16
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A

Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	16
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	16
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Attached
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT	*Pre*	0	*4 w*	*8 w*	*20 w*	*24 w*
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Phone call with researcher	X					
Allocation		X				
INTERVENTIONS:						
ACT Intervention			←	—	→	
Wait List Control						
ASSESSMENTS:						
BPI	X			X	X	
SF-12	X			X	X	
PGIC	X			X	X	
AAQ-II	X			X	X	
CHRONIC PAINAQ	X			X	X	
MULTiPleS	X			X	X	
PHQ-9	X			X	X	
GAD-7	X			X	X	
CSRI	X			X	X	
Qualitative Feedback						X

ACTION Pre-Questionnaire

Previous Next

0%

Before starting the programme, we're asking you to answer some questions about your health, experiences and the financial cost of your health conditions. At the end of the programme, we will ask similar questions and then, again, 3 months later to see if there have been any changes since starting the programme.

Some people don't like sharing details of their income – we understand this. Why we ask about income is that it helps us to see what percentage of income people spend on their health (for example, if someone has lots of money, €500 a year is not such a big deal; but if someone is on a low income, €500 is a lot and makes life harder).

These initial questions may take anywhere between 20 and 60 minutes to complete, so please make sure you are positioned comfortably over the next while and try to enjoy sharing your information in this way. We need you to fill in every question – the website will let you know if you have missed one so you can fill it in and continue.

All your answers will be held confidentially and anonymously in the Centre for Pain Research, NUI Galway.

At this point, we ask that you indicate if you consent to being a part of this study, now that you have read the information sheet that we emailed you, and understand what is being asked of you.

If you consent to answering these questions and taking part, select yes and click Next to continue. This will bring you to the start of the questionnaire and allow you to begin answering questions.

If you do not consent, select no and click Next to continue. This will exit you from the questionnaire, and will prevent you from going any farther in the study.
If you have any questions, please do not hesitate to ask us directly via email, painresearch@nuigalway.ie

Yes No

Previous Next

BMJ Open

The effectiveness of online Acceptance and Commitment Therapy (ACT) versus a waiting list control condition on pain interference and quality of life in adults with chronic pain and multimorbidity: Protocol for a randomised controlled trial

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Keywords:	Acceptance and Commitment Therapy, Online Intervention, Chronic Pain, Multimorbidity

Journal: BMJ Open

Title: The effectiveness of online Acceptance and Commitment Therapy (ACT) versus a waiting list control condition on pain interference and quality of life in adults with chronic pain and multimorbidity: Protocol for a randomised controlled trial

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Multimorbidity, Chronic Pain, Acceptance and Commitment Therapy, Internet, eHealth.

Abstract:

Introduction*:* Multimorbidity refers to the presence of two or more chronic health conditions within one person, where no one condition is primary. Research suggests that multimorbidity is highly correlated with chronic pain, which is pain lasting longer than 3 months. Psychotherapeutic interventions for people living with chronic illness have resulted in reduced symptom reporting and improved psychological well-being. There is a dearth of research, however, using online psychotherapy for people living with multimorbidity where chronic pain is a central condition. This study will compare the effectiveness of an online Acceptance and Commitment Therapy (ACT) intervention with a waitlist control condition in terms of improving health related quality of life (HRQoL) and reducing levels of pain interference in people with chronic pain and at least one other condition.

Methods and Analysis: 192 adult participants with non-malignant pain that persists for at least three months and at least one other medically diagnosed condition will be randomised to one of two study conditions. The experimental group will undergo an 8-session internet-delivered ACT-program over an 8-week period. A wait-list group will be offered the ACT intervention after the 3-month follow-up period. Health related quality of life and pain interference will act as the primary outcomes. Data will be analysed using a linear mixed model and adjusted to account for demographic and clinical variables as necessary. A Study Within a Trial (SWAT) will be incorporated to examine the effect on recruitment and retention of showing participants an animated educational video.

Ethics and dissemination: Ethical approval has been granted by the Research Ethics Committee of the National University of Ireland, Galway. Dissemination of results will be via peer reviewed journal articles and conference presentations.

Strengths and limitations of this study:

Strengths

- Interventions for people with chronic health problems tend to focus on one condition, and do not account for other symptoms or conditions a person may have.
- Research has shown that people with chronic pain typically have at least one other chronic health condition.To our knowledge this is the first randomised control trial to target the improvement of important health outcomes for people with chronic pain and multimorbidity. As such,
- The aims of this study are novel and would provide useful information for both the applied and research communities, as well as potentially reducing pain interference and improving HRQoL for patients.

Limitations

- This is the first study to adopt ACT for multimorbidity and chronic pain and there may be issues with the adaptation. That said, the adaptation for the current study was supervised by a clinical psychologist who specialises in ACT and chronic pain and we do not envisage any issues, moreover, the efficacy of the program as an intervention, is an empirical question and one which the study aims to answer.

INTRODUCTION

Background and Rationale

Multimorbidity

Multimorbidity is defined "as the co-existence of two or more chronic conditions, where one is not necessarily more central than the others" (Boyd & Fortin, [1] 2010, p.453). Traditionally, medicine has taken a single disease approach to the management of chronic conditions.[1]. However, as Boyd and Fortin amongst others [2,3] suggest, such an approach to disease management is becoming increasingly untenable as greater numbers of people present with multiple conditions In fact, as Violan et al.[4] highlight, multimorbidity is now considered the norm rather than exception in primary care patients and some, including Salisbury,[3] acknowledge that managing multimorbidity is the most important task facing health services in developed countries.

Risk factors & Prevalence

Prevalence estimates of multimorbidity vary from country to country. Recent research in Australia suggests that 25.5% of the population live with multimorbidity, [5] the prevalence of multimorbidity in Scotland is reported to be 23.2 %,[2] while in Ireland 45.3 % of the population are reported to have multimorbidity.[6] Indeed, prevalence rates of multimorbidity vary between subsets of different populations and are often found to be higher for those people who attend medical services. For example, Fortin and colleagues found that 90% patients in primary care in Canada had more than one condition,[7] while in an Irish study, 66.2% of patients in primary care had multimorbidity.[8]

Although prevalence rates vary across populations and groups, it is clear that increasing numbers of people are developing multimorbidity. The rise in multimorbidity is due in part to improving technology, advancements in medicine, and better health policies.[9] In terms of risk factors, research has shown that the most reliable predictor of multimorbidity is age. For example, one study found that the prevalence of two or more co-existing medical conditions in 18- to 44-year, 45- to 64-year, and 65-year and older age-groups were, 68%, 95%, and 99%, respectively.[7] However, while multimorbidity is positively correlated with age, it must be noted that it is not only the burden of older generations, as Agborsangaya et al [10] found that 70.2 % of their sample under the age of 65 live with multimorbidity. Other risk factors, including socioeconomic status, adverse childhood experiences,[6] poor physical activity, and risky health behaviours (e.g., smoking) are also important contributors to multimorbidity.[3]

Impact

Living with multiple chronic conditions has debilitating physical, psychological, social and financial consequences for a person and their family. Specifically, multimorbidity increases the risk of engagement with healthcare providers (i.e., hospitalisations), loss of physical functioning, depression, anxiety, polypharmacy, and ultimately has an impact on a person's health related quality of life (HRQoL).[11,12] HRQoL is a health outcome measure, which is an indicator of an individual's overall well-being, and it is typically used to assess the effectiveness of interventions; it is therefore a predictor of treatment success and it is increasingly used to support "allocation decisions in the health care sector".[13] Research has shown unequivocally that chronic disease has a negative impact on HRQoL; [11,12] and it has been found that having multiple chronic conditions has an exponential impact on a person's

well-being.[13] Therefore, there is an interaction effect rather than a cumulative effect of multimorbid chronic conditions on HRQoL.[13] Due to the increasing prevalence of multimorbidity and the burden of living longer with these conditions, the aim of improving HRQoL for people with multimorbidity has now become central to the focus of health practitioners.[14]

Chronic Pain and Multimorbidity

Chronic pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described by the patient in terms of such damage" that persists for a period in excess of 3 months. [15] Chronic pain is a major public health problem that can have debilitating physical, emotional, psychological, and financial consequences for those individuals living with it.[16–18] Prevalence estimates for chronic pain vary [12–14,19,20], however one recent study found that 35.5% of the Irish population were living with chronic pain. [14]

Chronic pain is highly correlated with multimorbidity, and is consistently identified as one of the most common conditions in those identified as having multimorbidity.[5] For example, in one Canadian study that examined the prevalence of disease-combinations, sixteen common disease pairs were identified, with chronic pain appearing in six of the combinations. Further, from the five most common disease triads identified in the same study, chronic pain was involved in three of these combinations.[5] Boyd and Fortin [1] noted that if a person had one chronic condition they were quite likely to also have another. Considering that over a third of the Irish population are reported to have chronic pain, and chronic pain is highly correlated with multimorbidity, it is important that research accounts for the relationship between the two.

Psychological Interventions for multimorbidity and chronic pain

Cognitive Behavioural Therapy (CBT) is frequently used when a psychological treatment is required as part of a multidisciplinary rehabilitative process for people with chronic conditions and has been employed widely, for example, with people who live with chronic pain.[8–13] Although CBT-based treatments are effective with many disorders, this is not the case for all conditions.[21] As a result, research has investigated the effects of other psychotherapeutic approaches. [22–24] Recently, Acceptance and Commitment Therapy (ACT) has been gaining support for improving HRQoL in people living with chronic conditions. [23,24]

Whereas CBT focuses on the reduction of symptom-related distress, ACT promotes 'psychological flexibility' (i.e., the ability to engage with the present moment in a way that facilitates long term values). From the perspective of ACT, increasing psychological flexibility for a person with a chronic condition is a multi-step process established by six core principles: acceptance of all experiences, both positive and negative; recognition of core personal values; committed action towards those values; psychological defusion; emphasis on the present moment; and sense of self as a context.[25] T ACT has been used as a psychological intervention to improve functioning and quality of life for people living with numerous chronic conditions, including depression,[26] tinnitus,[27] diabetes,[28] cancer,[29] post-traumatic stress,[30] and chronic pain.[31].

Indeed, a recent systematic reviews in the area of chronic pain [32] found that ACT interventions were effective when compared to inactive treatment comparisons for improving physical functioning and reducing distress. While, another systematic review of ACT in the context of chronic disease and long-term conditions found that while the number of high quality

research studies using ACT as an intervention was low, that there is promising evidence to suggest ACT can be efficacious as a treatment in a number of ways, including disease self-management. [33]

ACT Online

Traditionally, psychotherapeutic interventions, such as ACT, have been administered face-to-face when a client meets with a therapist. This face-to-face approach, however, is subject to numerous constraints including direct and indirect costs, high labour demands, long waiting lists, mobility and accessibility issues, and shortages in appropriately trained health care professionals.[34,35] The provision of one-to-one therapy is therefore not currently feasible for wide scale health interventions. To negate these limitations, researchers have begun to administer psychological interventions online. [21,36–41] These programs provide standardised psychological treatment over the internet and are promising in their cost-effectiveness and accessibility, as results have shown them to be efficacious.[41] For example, one recent randomised controlled trial examined the effectiveness of an online ACT intervention for people living with chronic pain.[42] Participants were randomly assigned to an online treatment group for 7 weeks or to a control group that participated in a moderated online discussion forum. Results showed that participants in the experimental group demonstrated increased activity engagement and willingness to experience pain and reductions were found on measures of pain-related distress, anxiety and depression. Furthermore, these improvements were maintained at a six-month follow-up.[42]

Objectives

There is a large body of research that supports the use of psychotherapy and internet-delivered psychotherapy for people living with chronic pain. However, there is a dearth of research that attempts to improve HRQoL for people living with multimorbidity using any form of intervention, and there is no research that specifically examines the delivery of any form of psychotherapy to improve HRQoL and reduce pain interference for people living with multimorbidity where chronic pain is a feature. Moreover, ACT interventions for people living with chronic illnesses tend to be symptom-specific and target a particular disease; however, it is clear that a large proportion of people with one chronic illness live with one or more additional chronic conditions. In light of these issues, the proposed randomised control trial will examine the clinical effectiveness of an internet-delivered ACT intervention for people living with multimorbidity featuring chronic pain. It is hypothesised that people in the ACT treatment group will report significant improvements in pain interference, HRQoL, physical functioning, emotional functioning and rating of overall improvement, relative to a waitlist control group.

Trial design

The design is a single-blind randomised controlled trial comparing the effect of an internet-delivered ACT intervention with a waiting list control condition on HRQoL and pain interference (primary outcomes) for people with multimorbidity where chronic pain is one of their conditions. This protocol will be reported in accordance with the SPIRIT guidelines (Supplementary File 1). [43]

METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

Study setting

The intervention is delivered in an online format and therefore participants can complete the intervention in their own homes. Study coordination and analysis will occur in the Centre for Pain Research at the National University of Ireland, Galway.

Eligibility Criteria

Inclusion criteria: aged at least 18 years; the presence of two or more chronic conditions (including chronic pain) reported by the patient as having been diagnosed by a doctor; resident of the Republic of Ireland; access to a computer/tablet and the internet; not currently undergoing any form of psychological treatment; sufficient competence in the English language (as determined by the participant) to complete the various elements of the study; informed consent is required. Exclusion criteria: severe cognitive impairment or psychiatric disorder that would interfere with the person's capacity to complete the study.

Patient Involvement

This study is based on a previous programme conducted at the Centre for Pain Research at NUI Galway [33]. Participant feedback (priorities, experiences and preferences), from that trial, and the pilot for this RCT were incorporated into the design of the intervention and the data collection. Patients will not be formally involved in recruitment for the study, but patient advocacy groups will be involved in promoting the study. We will communicate the results to participants by email when they are available.

Interventions

Experimental Group

The treatment protocol is almost identical to that used in a previous study by Hayes et al. examining the clinical and cost effectiveness of an internet-delivered ACT intervention for people living with chronic pain.[35] The intervention was derived from an ACT treatment manual specifically devised for people with chronic pain [44] and adapted for online dissemination. Hayes et al. utilised other resources [45–47] and a team of healthcare professionals, including physiotherapists and clinical psychologists who specialise in chronic conditions and ACT treatments to revise the material so that it was modified accordingly and was suitable for online delivery. [35] Thus, the online ACT treatment designed by Hayes et al. is a robust adaptation and has been adopted for the purposes of the current research.

Appropriate changes to the content were made, so that the ACT programme designed by Hayes et al. can be used in the current study for people with multiple conditions rather than for chronic pain only. The core concepts, homework, metaphors, and mindfulness exercises, have for the most part, not been altered in any way. The only amendments necessary to the

Hayes et al. ACT treatment program were to alter the content that referred to symptoms of chronic pain specifically to instead refer to living with multimorbidity.

The experimental treatment will consist of eight sessions over an eight-week period and will be hosted on the NUI Galway, Centre for Pain Research Website. The program will be delivered via an interactive online platform, and will consist of information, homework assignments, relevant metaphors and mindfulness exercises. The focus of this treatment protocol is on increasing psychological flexibility by developing acceptance, present-focused awareness and engagement in values-based action. An overview of the treatment is provided in Table 1.

Over the course of the trial, participants in the experimental group will receive an automated weekly email reminder to complete each session. Adherence to the intervention will be monitored through login data. There is no clinician contact, and the programme is self-guided, with researchers only contacting participants (by phone or email) to prompt them should they fall behind. If a participant wishes to discontinue their involvement they will be withdrawn from the intervention and this will be reported as attrition. Technical questions and other queries are answered by email by the research team.

Wait-list control group

The waitlist control group will continue with their usual care, and will be contacted by the research team to complete questionnaires at 8 weeks post allocation and at 3 months follow up. They will then be offered the opportunity to use the online ACT intervention following the 3-month follow-up assessment.

Table 1: Overview of the internet-delivered ACT intervention program

Week	Session	Summary of content
1	Session 1	• Introduction to the ACT program and program overview • Review of treatment history and evaluate it in terms of how it has worked relative to the participant's goals and expectations • Review the interactions between thoughts, feelings and function, which often serve to make each other worse (e.g. become a "vicious cycle") • Introduce the idea that change is possible - not based on symptom reduction but on aiming to alter function • Introduction to mindfulness technique • Homework assignment: check in with self daily and focus on activities
2	Session 2	• Introduction to the concept of acceptance and how one's experiencing of their symptoms from their various conditions may limit participation in valued activities • Explanation of values • Mindfulness explanation & debrief • Homework assignment: Mindfulness practice daily
3	Session 3	• Identification & clarification of values • Assessment and rating of values • Discrepancy between values and current function • Leave on a stream mindfulness exercise • Mindfulness debrief • Homework assignment: Mindfulness practice daily
4	Session 4	• Barriers to pursuing values • Overcoming barriers • Swamp metaphor - exercise exploring the possibility for values-based action even with aversive experiences. Discussion on the concept of willingness and unwillingness to have discomfort • Body scan mindfulness exercise
5	Session 5	• Goal setting exercise in line with 3 chosen values • Discussion on fluctuating levels of high and low functioning and benefits of activity pacing in order to achieve a more consistent level of activity from day to day. • Homework assignment: Record performance over the next week regarding carrying out specific actions and pacing of activities and practice mindfulness every day.
6	Session 6	• "Tricks of the mind" exercises to raise awareness of language-based influences on function • Cognitive defusion exercises - Finding a place to sit metaphor, Get off your Buts exercise, Milk exercise, Passengers on a bus Exercise and "buying" thoughts. • Homework assignment: practice mindfulness and cognitive de-fusion techniques daily
7	Session 7	• Planning and action • Willingness and Committing to action • Mindful Walking exercise • Homework assignment: commit yourself to action

8	Session 8	• Emphasis on commitment to actions and values even when barriers exist and future planning - this is a "lifelong assignment" • Preparation for relapses and setbacks • End of programme • Recap on topics covered throughout the programme

Outcome measures

Demographic and clinical information

Participants will be asked to provide details regarding age, gender, highest educational attainment, occupational status and relationship status as well as number and type of chronic conditions and duration of their conditions (including BMI) using a multimorbidity checklist. Some details about previous and current medical and alternative treatment will also be collected.

Primary outcome measures

Brief Pain Inventory (BPI) - Short form

The BPI-Short form [48] is a 9-item instrument that measures the interference and severity of a person's pain and the impact of their pain on their daily functioning, and is a standardised and widely used measurement tool for assessing chronic pain. The first eight items ask the person to provide demographic information, medicinal measures to alleviate pain symptoms, to identify locations of pain, and to rate their pain severity from 1-10 (10 being the most severe pain) on a visual analogue scale over the past 24 hours. Item 9 is further divided into seven sub-items, examining interference with function. The sub-items can then be grouped into those assessing physical functioning (i.e., general activity, walking ability, and working ability), those assessing psychological functioning (i.e., mood, relations with other people, and enjoyment of life) and one item investigating the extent to which pain affects sleep. The BPI has demonstrated good construct validity, adequate internal consistency,[49] Cronbach's alpha, $\alpha = 0.88$ and acceptable test-retest reliability.[50]

12 Item Short Form Survey (SF-12)

The SF-12 is a standardised instrument used as a measure of HRQoL.[51] A shortened version of the SF-36,[52] it reduces participant burden while still providing sub-scale scores across eight health domains (general health, physical functioning, emotional role limitation, physical role limitation, mental health, bodily pain, vitality and social functioning). It also produces two summary scores, a Mental Component Summary (MCS) and a Physical Component Summary (PCS) of HRQoL [53] with lower scores on these scales representing lower quality of life. Both the overall score and the summary scores will be analysed, although the overall score will be the one of interest as primary outcome.

Secondary outcome measures

The Acceptance and Action Questionnaire II (AAQ-II)

The original AAQ [54] has been used extensively with chronic conditions [29,55,56] and the AAQ-II [53] is widely used in measuring psychological inflexibility and experiential avoidance. The AAQ-II is a seven item questionnaire, in which participants rate their responses to each item on a 1-7 scale in terms of how likely they are to accept or avoid aversive thoughts and feelings (1 = 'never true' and 7 = 'always true'). The higher the participant scores overall, the greater the level of psychological flexibility. While there have been criticisms of the AAQ-II [54] it has good content, construct, convergent and predictive validity [49] and satisfactory reliability.[57]

Chronic Pain Acceptance Questionnaire-8 (CPAQ-8)

The CPAQ-8 [58] the shortened version of the Chronic Pain Acceptance Questionnaire (CPAQ) [53] is an eight item questionnaire and is rated on a scale from 0 to 6 (0= 'never true' and 6= 'always true'). The questionnaire contains two subscales; pain willingness and activity engagement, which are summed to indicate overall acceptance of pain. The CPAQ-8 has been validated in various populations [59,60], has adequate to good reliability and consistency with Cronbach's alpha coefficients ranging from 0.69 to 0.86, and good test-retest reliability with an overall score correlation of 0.81.[61]

Multimorbidity Illness Perceptions Scale (MULTiPleS)

The Multimorbidity Illness Perceptions Scale (MULTIPleS) [62] was developed to measure patient illness perceptions in the context of MM. Illness perceptions are a person's thoughts and feelings about their disease. The MULTIPleS is a 22 item questionnaire. The respondent indicates their level of agreement with each item on a Likert scale; the first 16 item scores range from 0 to 3, where '0' indicates that a person 'strongly disagrees' with an item and '3' indicates that a person 'strongly agrees' with an item, and the remaining 6 items range from 0 to 5. Overall, the 22 items comprise five subscales; emotional representation, treatment burden, prioritising conditions, causal link, and activity limitations. We will analyse the responses to the MULTIPLeS across our three time points to assess for change overall or in these subscales. The MULTIPleS is relatively new - Gibbons et al. [62] found that the scale provided a good fit to the Rasch model and demonstrated evidence of reliability and validity for each of the subscales.

Patient Health Questionnaire (PHQ-9)

The PHQ-9 is a widely used measure of depression.[63] Items relate to the criteria for depression in the DSM V, and are scored on a 4 point Likert scale, ranging from 0 ("not at all") to 3 ("nearly every day"). Higher scores indicate the person meets more of the symptom criteria; scores above 10 indicates moderate depression, and scores above 15 indicates a clinical case of moderately severe depression. It has been used and validated with chronic condition populations.[17]

GAD-7

The GAD-7 a validated and standardised measure, will be used to measure anxiety.[64] The seven item questionnaire presents items relating to how often over the past couple of weeks a person has felt bothered by the seven DSM V criteria symptoms of generalized anxiety

disorder. Items are scored on 4 point Likert scales ranging from 0 "not at all" to 3 "nearly every day". A higher overall total score indicates greater symptom severity.

Client Services Receipt Inventory (CSRI)

The CSRI [65] has been used widely in research examining the cost of CP [18,66,67] and has been shown to be a valid measure of frequency of health service use.[68] Medication and health service use will be measured at baseline, post-treatment and follow-up, using a modified version of the CSRI. As medication use will most likely vary throughout the trial, change in medication use (including prescribed and over-the-counter medications) will be examined in post-treatment analysis.

Study timeline

Interested participants will complete a screening questionnaire that will determine whether they satisfy the inclusion criteria, they will then complete another questionnaire that will capture demographic information and baseline data. Potential participants will receive a scripted phone call involving a further explanation and an opportunity to ask questions. They will then be randomised online to either the intervention or control group. Both groups will be asked to complete questionnaires at post intervention (8 weeks) and at follow up (3 months). Participants in the wait list control will then receive access to the program. The process is outlined in the schematic diagram of participant flow (Supplementary File 2). As a point of note, a Study Within a Trial will be conducted examining the effect of a short video on retention.

Sample size

In line with statistical convention and Cohen's recommendations,[69] a sample size of 77 per group (total = 154) will have the desired power of .8, with a .025 alpha level to detect a medium effect size (d = .50 to .79) and both a significant clinical (i.e., 5 point difference or one-half its standard deviation)[68] and statistical difference in HRQoL between the experimental and control groups based on a two-tailed independent samples t-test. In accordance with the results of a previous study using online ACT for chronic pain [42] , using an alpha value of 0.025 and a desired power of 0.8, a total of 124 participants (62 per arm) are required to detect a medium difference in pain interference between the experimental and control groups. When calculating both sample sizes, an alpha value of 0.025 was used to account for multiple primary outcomes.

In order to detect both primary outcomes, the larger sample of 154, will be used. A recent study protocol with a similar design to the current study reported an expected 20% participant attrition rate between Time 1 and Time 3.[42] To take account of this potential attrition rate, 192 participants will be recruited in the current study (96 per arm).

Recruitment

Participants will be recruited through advertisements about the study across a variety of contexts. Advertising will be done through websites that provide information on various chronic conditions typically found in an Irish context. Advertisements will also be posted in any relevant publications, forums, or discussion boards where potentially interested parties are identified and through social media and the website of the Centre for Pain Research at NUI

Galway. Furthermore, information will be given to relevant healthcare professionals, groups and communities to disseminate about the trial as they see fit. Interested people will be directed to a website (Centre for Pain Research, at NUI Galway) where the trial is based, and encouraged to read additional information about the trial before they sign up. Potential participants will be told they can contact the research team should they have any questions or wish to clarify any information before they apply to participate.

METHODS: ASSIGNMENT OF INTERVENTIONS

Allocation

When a participant agrees to take part in the trial they will be randomly assigned to the intervention or waiting list control group using random permuted blocks to ensure groups are balanced. Randomisation will be performed using a custom-written script, administered from a password-secured server. As such, researchers do not hold influence in the allocation process.

Blinding

For initial analysis, the data analyst will be blinded to group allocation; however, because the trial delivers a psychological intervention it is not possible to blind the participants to the groups they are in.

METHODS: DATA COLLECTION, MANAGEMENT, AND ANALYSIS

Data Collection Methods

All outcome measures administered at pre-intervention, post-intervention and at 3-month follow up are self-report and will be conducted online using the survey software Limesurvey (www.limesurvey.com). The participant attrition rate and any adverse events that may occur for the participants while they complete the intervention will also be recorded. Unless participants formally discontinue the study, attempts will be made to collect outcome data.

Data Management

All study information will be collected online, using surveying software installed on a secure server managed by the research team at the Centre for Pain Research, School of Psychology. NUI Galway. The software and server are password protected and only two members (BMcG and LOC) of the team hold the password. Non-identifiable information will be exported from the surveying software as needed, and shared only with the research team on secure computers based within the Centre for Pain Research at NUI Galway.

Statistical Methods

Data will be analysed using the principles of intention-to-treat analysis. Date will be summarised by appropriate graphical (e.g., box plots, labelled scatter plots and case profile plots) and numerical methods (e.g., frequency counts, means, medians, standard deviations, and quartiles). The first primary outcome measure, the SF-12, produces scores on eight subscales and two summary scores, which are transformed into a 0-100 scale. As such, the data

from the SF-12 will be treated as a continuous variable [70] and the data from this measure over time (e.g., baseline versus post-intervention versus 6-month follow-up) will be analysed using a linear mixed model and adjusted accordingly to account for demographic and clinical variables as necessary. The second primary outcome, pain interference, measured by the BPI short-form, is scored by calculating the mean of seven different interference items; walking, work, mood, enjoyment of life, relations with others, sleep, and general activity. The pain interference data is rated on a scale of 0-10 and will be treated as a continuous variable and analysed as above. The secondary outcome measures will be treated as continuous variables also and analysed in a similar fashion. However, the PGIC yields ordinal data and as such a non-linear method will be employed to analyse this information. Each hypothesis will be tested using a two-tailed analysis at $\alpha = 0.05$ level of significance and missing data will be treated using multiple imputation analysis. A Bonferroni adjustment will be applied to results in order to account for the presence of multiple outcomes. All analyses will be completed using SPSS version 22 [71] and Stata IC 13.[72]

METHODS: MONITORING

Data Monitoring

All study information will be collected online, using surveying software installed on a server managed by the research team. The software and server are password protected. Non-identifiable information will be exported from the surveying software as needed, and shared only with the research team.

Adverse events

Adverse events will be recorded. No harm is anticipated to arise from participating in this study. However, as with any psychotherapeutic intervention there is a slight chance that some content or their participation will cause distress to some participants. Participants will be made aware, should such an event arise, to contact a member of the research team who will refer them to appropriate support services. In addition, clinical staff within the Centre for Pain Research will be on hand to offer additional support if necessary.

ETHICS AND DISSEMINATION

Research ethics approval

Ethical approval has been granted by the National University of Ireland Galway Research Ethics Committee ref: ('NUI Galway Research Ethics Committee 16/JAN/01')

Protocol amendments

In the event that amendments are made to the protocol, the trial registration will be updated. This study is based on a previously run study, as such significant changes are not anticipated, in the event that changes occur they will be communicated to participants via email.

Consent

Consent will be obtained electronically prior to enrolling in the study (Supplementary File 3). In addition, a phone call will offer participants the chance to formally withdraw before allocation.

Confidentiality

All study-related information will be stored securely at the Centre for Pain Research, School of Psychology, NUI Galway, where the research is taking place. Electronic data will only be accessible to the research team and will be stored on secure computers that are password-protected.

Declaration of interests

The authors declare that they have no competing interests.

Access to data

Members of the research team will have access to the data during analysis. Anonymised participant level data and statistical code will also be available to researchers upon request.

Ancillary and post-trial care

Given the nature of the study, it is not anticipated that participants will experience adverse effects. In the event that this occurs, participants are encouraged to contact the research team for further advice.

Dissemination policy

The findings of the trial will be submitted for publication in peer-reviewed journals and will be disseminated through conference presentations.

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Protocol Version 1, 25/04/18

Author Contributions

BWS, LO'C, KB, SH are involved in the design, delivery and evaluation of the trial and also drafted the manuscript. KF, CPD, SO'H, LC, and JE were involved in the editing of the manuscript and will be involved in the evaluation of the trial. BMcG contributed to the design of the intervention, supervises the delivery and evaluation of the study, and contributed to editing the manuscript.

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Competing interests

The authors declare that they have no competing interests.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page No
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	24
Funding	4	Sources and types of financial, material, and other support	24
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 24
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-7
	6b	Explanation for choice of comparators	
Objectives	7	Specific objectives or hypotheses	7

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	8-10
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8-10
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10-12
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12-13 & Appendices
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	14
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	14
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	14
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	14
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	14
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	14
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15

Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	15
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	15
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	15
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	16
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	16
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	16
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A

Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	16
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	16
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Attached
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT	*Pre*	0	*4 w*	*8 w*	*20 w*	*24 w*
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Phone call with researcher	X					
Allocation		X				
INTERVENTIONS:						
ACT Intervention			←	—	→	
Wait List Control						
ASSESSMENTS:						
BPI	X			X	X	
SF-12	X			X	X	
PGIC	X			X	X	
AAQ-II	X			X	X	
CHRONIC PAINAQ	X			X	X	
MULTiPleS	X			X	X	
PHQ-9	X			X	X	
GAD-7	X			X	X	
CSRI	X			X	X	
Qualitative Feedback						X

ACTION Pre-Questionnaire

Previous Next

0%

Before starting the programme, we're asking you to answer some questions about your health, experiences and the financial cost of your health conditions. At the end of the programme, we will ask similar questions and then, again, 3 months later to see if there have been any changes since starting the programme.

Some people don't like sharing details of their income – we understand this. Why we ask about income is that it helps us to see what percentage of income people spend on their health (for example, if someone has lots of money, €500 a year is not such a big deal; but if someone is on a low income, €500 is a lot and makes life harder).

These initial questions may take anywhere between 20 and 60 minutes to complete, so please make sure you are positioned comfortably over the next while and try to enjoy sharing your information in this way. We need you to fill in every question – the website will let you know if you have missed one so you can fill it in and continue.

All your answers will be held confidentially and anonymously in the Centre for Pain Research, NUI Galway.

At this point, we ask that you indicate if you consent to being a part of this study, now that you have read the information sheet that we emailed you, and understand what is being asked of you.

If you consent to answering these questions and taking part, select yes and click Next to continue. This will bring you to the start of the questionnaire and allow you to begin answering questions.

If you do not consent, select no and click Next to continue. This will exit you from the questionnaire, and will prevent you from going any farther in the study.
If you have any questions, please do not hesitate to ask us directly via email, painresearch@nuigalway.ie

Yes No

Previous Next