

BMJ Open Comparing the clinical-effectiveness and cost-effectiveness of an internet-delivered Acceptance and Commitment Therapy (ACT) intervention with a waiting list control among adults with chronic pain: study protocol for a randomised controlled trial

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ABSTRACT

Introduction: Internet-delivered psychological interventions among people with chronic pain have the potential to overcome environmental and economic barriers to the provision of evidence-based psychological treatment in the Irish health service context. While the use of internet-delivered cognitive-behavioural therapy programmes has been consistently shown to have small-to-moderate effects in the management of chronic pain, there is a paucity in the research regarding the effectiveness of an internet-delivered Acceptance and Commitment Therapy (ACT) programme among people with chronic pain. The current study will compare the clinical-effectiveness and cost-effectiveness of an online ACT intervention with a waitlist control condition in terms of the management of pain-related functional interference among people with chronic pain.

Methods and analysis: Participants with non-malignant pain that persists for at least 3 months will be randomised to one of two study conditions. The experimental group will undergo an eight-session internet-delivered ACT programme over an 8-week period. The control group will be a waiting list group and will be offered the ACT intervention after the 3-month follow-up period. Participants will be assessed preintervention, postintervention and at a 3-month follow-up. The primary outcome will be pain-related functional interference. Secondary outcomes will include: pain intensity, depression, global impression of change, acceptance of chronic pain and quality of life. A qualitative evaluation of the perspectives of the participants regarding the ACT intervention will be completed after the trial.

Ethics and dissemination: The study will be performed in agreement with the Declaration of Helsinki and is approved by the National University of

Ireland Galway Research Ethics Committee (12/05/05). The results of the trial will be published according to the CONSORT statement and will be presented at conferences and reported in peer-reviewed journals.

Trial registration number: ISRCTN18166896.

INTRODUCTION

Chronic pain is a common condition that affects between one in three¹ and one in six adults.² It is a major public health problem that often runs a relapsing and recurrent course and 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 which persists for a period in excess of 3 months.³ While chronic pain can be associated with a number of progressive or degenerative conditions, it most commonly occurs in people with benign medical conditions such as musculoskeletal problems. For many people, the presence of chronic pain has adverse effects on their daily functioning, employment, relationships and emotional functioning.^{1 2} Considering its associated direct and indirect expenditures, chronic pain is also a costly social phenomenon.^{1 2 4} A recent estimate of the cost of chronic pain in Ireland was €5.34 million, or 2.86% of the gross domestic product per year.⁵

Cognitive-behavioural therapy (CBT) is the standard psychological treatment for people

with chronic pain^{6–11} and it underpins many of the interdisciplinary pain management programmes. However, it is apparent that some people who experience chronic pain do not benefit from CBT interventions.^{11–14} Therefore, clinicians and researchers continue to examine alternative forms of psychological treatment for this large clinical population. The primary aim of CBT is to control and minimise pain-related distress; however, in recent years, there has been a shift towards strategies that promote the acceptance of pain. The Acceptance and Commitment Therapy (ACT)¹⁵ treatment model consists of awareness and non-judgemental acceptance of all experiences, both positive and negative; identification of valued life directions and appropriate action towards goals that support those values.^{15–16} The aim of ACT is to increase functioning and decrease interference of pain with value-driven action.¹⁶ The empirical support for ACT has increased considerably in recent years. Until now, there are at least eight randomised controlled trials in support of the efficacy of ACT programmes in the management of chronic pain.^{16–23} A wide array of methods of programme delivery have been evaluated, including variations of duration of treatment sessions, method of delivery of ACT sessions (group, one-to-one, internet-delivered or self-help) and length of ACT intervention (ranging from 4 to 10 sessions). The results of a systematic review and meta-analysis of the literature demonstrated that acceptance-based therapies have small but consistent effects on physical and mental health among people with chronic pain (standardised mean differences (SMD's) 0.37 to 0.41),¹¹ which are comparable to those of CBT (SMD's -0.15 to -0.21).⁹

Traditional multidimensional rehabilitation for people with chronic pain requires expensive specialised clinics.^{19–24} Access to ACT treatment programmes and other psychological treatment programmes is often limited due to various individual and systemic barriers including direct and indirect costs, mobility limitations, long waiting lists and insufficient numbers of appropriately trained health professionals.^{24–25} One approach that aims to increase access to psychological intervention which has received increased attention in recent years is internet-delivered psychological therapy.^{22–24–26–30} Such internet-delivered programmes provide standardised evidence-based psychological treatment at minimal cost and interference for people with chronic pain.^{19–31} Recently, one randomised controlled trial has examined the clinical-effectiveness of a guided internet-based ACT intervention among 76 people with chronic pain.²² The results demonstrated that participants who received the ACT intervention demonstrated significant improvements regarding activity engagement and willingness to experience pain symptoms at both postintervention and at 6-month follow-up, compared with people who partook in a moderated online discussion forum. Furthermore, the authors called for future investigation of the costs and cost-savings of an online ACT intervention for people with chronic pain.

The significant cost of chronic pain internationally¹ and in Ireland^{4–5} provides a clear rationale for the current study to focus on the economic evaluation of an internet-delivered ACT intervention. A thorough understanding of the economic cost of chronic pain is crucial to inform decision-making regarding health service resource allocation, especially for high-intensity service users.⁴ This aspect of the study will be conducted with a view to giving more affordable alternative options to the current chronic pain management services in Ireland.

Given the limited number of randomised controlled trials of ACT interventions for chronic pain and specifically internet-guided ACT interventions, the present study aims to examine the clinical-effectiveness and cost-effectiveness of an internet-delivered ACT treatment programme among a sample of people with chronic pain. It is hypothesised that people in the ACT treatment group will report significant improvements on measures of pain intensity, physical functioning, emotional functioning and rating of overall improvement, relative to a wait-list control group.

METHODS AND ANALYSIS

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 in the management of chronic pain. Any modifications to the protocol which may impact on the conduct of the study will require a formal amendment to the protocol. Such amendment will be agreed on by the Irish Health Research Board Interdisciplinary Capacity Enhancement Award, grant number (ICE/2011/19) research group, and approved by the relevant ethics committee prior to the implementation of the modifications. Minor administrative changes to the protocol will be agreed on by the Irish Health Research Board Interdisciplinary Capacity Enhancement Award, grant number (ICE/2011/19) research group, and will be documented in a memorandum.

Recruitment, participants and randomisation

Recruitment of the participants will be conducted via advertisements about the trial on websites which offer information and services to people with chronic pain and via advertisements in local general practitioner and physiotherapy clinics. People who are interested in taking part in the trial will be invited to contact the Centre for Pain Research via phone or email, wherein they will be given an opportunity to ask questions about the trial. When contacted, the researcher will explain the study in detail. Interested people will be directed to the trial website where they will be encouraged to read additional information about the trial (see online supplementary appendix 1) and apply to participate. Selection criteria are: aged 18 years or more, the presence of pain for at least 3 months duration, resident of Ireland, regular access to a computer and to the

internet, not currently undergoing any other form of psychological intervention for chronic pain, not currently experiencing a psychotic illness (screened with a Health Problems Questionnaire),³² not experiencing chronic pain due to malignancy and adequate English language ability. Participation in any other form of psychological intervention for chronic pain in addition to the study intervention is prohibited during the trial. All participants will provide full informed consent. Participants will be randomised to the intervention or waiting list control group using random permuted blocks to ensure that the groups are balanced periodically. The randomisation process will be performed by a web-based password secured and encrypted data management system designed specifically for the randomisation of participants into clinical trials. Once the randomisation procedure has been completed, the participants in the online ACT intervention group will begin the intervention. The statistician involved in the analysis of the data will be blinded to group allocation. As the study involves a psychological intervention with a waitlist control group, blinding of the participants will not be possible.

TREATMENT REGIMENS

The internet-delivered ACT intervention will consist of eight sessions over an 8-week period and is based on an unpublished manual used in a previous study of people with chronic pain.³³ Other relevant resources and literature were also used in designing the online ACT programme.^{15 34 35} The programme will be delivered via the interactive online platform *Lifeguide* (<http://www.lifeguideonline.org/>). It will consist of information, homework assignments, relevant ACT metaphors and mindfulness exercises. This treatment protocol is focused on the promotion of acceptance, present-focused awareness and engagement in value-based action. Detailed information about the content of the treatment programme is outlined in [table 1](#). The current ACT intervention has been developed into an online format by a postdoctoral clinical psychologist who has experience in psychological and behavioural treatment of chronic pain (HD) and a postdoctoral physiotherapist (SH) under the supervision of a licensed clinical psychologist specialising in pain management (BM) and a psychologist with expertise in the ACT approach (MH). In addition, qualitative one-to-one interviews will be conducted with an opportunistic sample of individuals with chronic pain to explore their perception of the main problems posed by chronic pain to functioning and participation in important areas of their lives. Following content analysis, the insights gained from the qualitative data will be incorporated into the ACT intervention. Each of the sessions will be subjected to as many reviews as necessary, by both the research team and individuals with chronic pain, to ensure that both interface and content are understandable, engaging and have the potential to achieve the aim of the internet-delivered ACT intervention, that is,

increase functioning and decrease interference of pain with value-driven action. To maximise participant engagement and experiential learning, all aspects of this programme will include audio and visual presentations. Each lesson will begin with a summary of previous lessons and an introduction to the contents of the current lesson. Summaries of key points will be outlined in each lesson, and concepts and skills described in earlier lessons will be repeated and combined in later lessons. Weekly emails will be sent to participants, wherein they will be notified of new content and reminded about the course material that they have not accessed.²⁴ Participants will also receive weekly phone calls from a member of the research team throughout the duration of the intervention. The phone calls will be structured and will aim not only to motivate and encourage the participants but also to give them the opportunity to ask questions about the intervention. However, the phone calls are not intended to form part of the therapy per se. Adherence to the trial intervention will be monitored automatically via the online delivery platform (*Lifeguide*) and adherence to the trial assessments will be monitored automatically via the online survey provider. If a participant wishes to discontinue their assigned intervention, access to the intervention will be withdrawn from the participant and this will be reported as attrition. However, in an attempt to enable follow-up data collection and prevent missing data, the study participant will be retained in the trial whenever possible.

Participants allocated to the waitlist control condition will not receive the internet-delivered ACT intervention at that time. They will be contacted by the postdoctoral researcher to explain that they have been allocated to the waiting list control group, at which time they will be given an opportunity to ask questions regarding the trial. All participants, including the waitlist control group, will be offered the opportunity to utilise the online ACT intervention after the 3-month follow-up assessment.

OUTCOME MEASURES

All outcome measures are self-reported and will be conducted during the week immediately preintervention, during the week immediately postintervention and at a 3-month follow-up. Participants will receive instructions on how to complete each self-report measure according to standardised instructions for each measure of outcome. The outcome measures chosen for inclusion in this trial are based on the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations for outcome measures for chronic pain clinical trials.¹² The four core chronic pain outcome domains will be measured, namely: pain intensity, physical functioning, emotional functioning and participants' rating of overall improvement. Any adverse events and the rate of attrition among the participants during their

Table 1 Overview of the internet-delivered Acceptance and Commitment Therapy (ACT) intervention programme

Week	Session	Summary of content
1	Session 1	<ul style="list-style-type: none"> ▶ Introduction to the ACT programme and programme overview ▶ Review treatment history and evaluate it in terms of how it has worked relative to the participant's goals and expectations ▶ Review interactions between thoughts, feelings and function, which often serve to make each other worse (eg, 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—which is followed by the mindfulness debrief regarding the participants' experiences of mindfulness
2	Session 2	<ul style="list-style-type: none"> ▶ Introduction to the concept of acceptance and how one's experience of pain may limit participation in valued activities ▶ Values clarification exercises ▶ Mindfulness and debrief ▶ Homework assignment: mindfulness practice daily
3	Session 3	<ul style="list-style-type: none"> ▶ Identification of values ▶ Assessment and rating of values ▶ Discrepancy between values and current function ▶ Mindfulness of breath exercise ▶ Mindfulness debrief ▶ Homework assignment: mindfulness practice daily
4	Session 4	<ul style="list-style-type: none"> ▶ Barriers to pursuing values ▶ Overcoming barriers ▶ Swamp metaphor—exercise exploring the possibility for value-based action even with aversive experiences. Discussion on the concept of willingness and unwillingness to have discomfort ▶ Body scan mindfulness exercise
5	Session 5	<ul style="list-style-type: none"> ▶ Goal setting exercise in line with three 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
6	Session 6	<ul style="list-style-type: none"> ▶ 'Tricks of the mind' exercises to raise awareness of language-based influences on function ▶ Cognitive defusion exercises—'catch' your thoughts and label them ▶ Homework assignment: practice mindfulness and cognitive defusion techniques daily
7	Session 7	<ul style="list-style-type: none"> ▶ Planning and action ▶ 'Act On'=Taking the 'I' out of action ▶ Homework assignment: commit yourself to action
8	Session 8	<ul style="list-style-type: none"> ▶ End of programme ▶ Emphasis on commitment to actions and values even when barriers exist and future planning—this is a 'lifelong assignment' ▶ Preparation for relapses and setbacks

completion of the intervention will also be recorded. Additional measures of potential confounding variables will be included to allow for the accounting of these variables in the analyses.

Demographic and clinical information

Participants will be asked to supply details regarding age, gender, highest educational attainment, occupational status and relationship status as well as duration of chronic pain, site(s) of chronic pain and cause of chronic pain. Some details about previous and current medical and alternative treatment will also be collected.

Primary outcome measure

Brief pain inventory-short form

The Brief pain inventory-short form³⁶ measures pain severity and the degree of interference with function, using a numerical rating scale from 0 to 10. The interference scale is a seven-item self-report measure, designed to assess the extent to which pain interferes with various components of functioning, including physical and emotional functioning and sleep. The items in this scale can be grouped into those that assess physical functioning (general activity, walking ability, normal work, including work outside the home and housework), those that assess emotional functioning (mood, relations with people, enjoyment of life) and a single item that

assesses the extent to which pain interferes with sleep. Tan *et al*³⁷ reported acceptable internal consistency for the interference scale (Cronbach's α , $\alpha=0.88$). Excellent test-retest reliability of the BPI has also been demonstrated among people with chronic pain due to osteoarthritis.³⁸ Correlation coefficients ranging from $r=0.83$ – 0.88 and from $r=0.83$ – 0.93 were reported for the pain intensity and for the pain interference scales, respectively.³⁸ Reductions in pain intensity between 10% and 20% represent a minimal clinically meaningful change and a reduction of one point on the interference scale has been recommended as a clinically meaningful change among people with chronic pain.³⁹

Secondary outcome measures

Beck depression inventory

The Beck Depression Inventory (BDI)^{40–41} consists of 21 groups of four statements designed to assess the severity of current symptoms of depressive disorders, with total scores on the measure ranging from 0 to 63. Previous literature demonstrates acceptable internal consistency (Cronbach's α 0.73–0.95), test-retest reliability (r 0.80–0.90), convergent validity (mean $r=0.60$) and responsiveness to change of the BDI.^{39–42}

Pain Anxiety Symptoms Scale-20

The Pain Anxiety Symptoms Scale-20 (PASS-20)⁴³ is a 20-item scale which measures pain-specific anxiety symptoms and consists of four five-item subscales measuring cognitive anxiety responses, escape and avoidance, fearful thinking and physiological anxiety responses. All items are measured on a frequency scale ranging from 0 (never) to 5 (always).⁴⁴ Psychometric evaluation of the PASS-20 demonstrated that this scale has strong internal consistency (Cronbach's α 0.75–0.91) and convergent validity (mean r 0.95) and adequate construct validity (r 0.24–0.69).⁴⁴

Patient Global Impression of Change

The Patient Global Impression of Change (PGIC) scale⁴⁵ was recommended by IMMPACT for use in chronic pain clinical trials as a core outcome measure of global improvement with treatment.³⁹ This single-item rating by participants of their response during clinical trials uses a seven-point rating scale with the options 'very much improved', 'much improved', 'minimally improved', 'no change', 'minimally worse', 'much worse' and 'very much worse'. The percentages of the participants endorsing each of the seven response options in each group will be analysed and reported separately.

Chronic Pain Acceptance Questionnaire-8

The Chronic Pain Acceptance Questionnaire-8 (CPAQ-8)⁴⁶ is a short version of the CPAQ⁴⁷ and consists of eight items which measure activity engagement and pain willingness, which reflect the central tenets of ACT. Each item is scored on a Likert scale ranging from 0, 'never true', to 6, 'always true', and higher scores

indicate greater activity engagement and pain willingness. The internal consistency and the test-retest reliability of the CPAQ are well established (Cronbach's α 0.72–0.92 and interclass correlation coefficient=0.86; 95%CI 0.81 to 0.90), respectively.^{48–51} Recent confirmatory factor analyses provide further support for the two-factor structure of the original scale.^{52–53} In addition, the CPAQ-8 has been validated in samples of people with chronic pain.^{46–51–54–55}

EQ-5D

EQ-5D is a standardised instrument for use as a measure of health-related quality of life (HRQOL) outcome. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status. The EQ-5D descriptive system will be included which asks respondents to assess their mobility, self-care, usual activities, pain/discomfort and anxiety and depression on a five-point scale: no problems, slight problems, moderate problems, severe problems and extreme problems. The EQ Visual Analogue Scale (EQ VAS) will also be included which records the respondent's self-rated health on a vertical VAS where the end points are labelled 'best imaginable health state' and 'worst imaginable health state'. The EQ-5D has been shown to have good construct validity and responsiveness among people with chronic pain.⁵⁶

Client Service Receipt Inventory

Medication and health service use will be measured at baseline, post-treatment and follow-up, using the pain version of the Client Service Receipt Inventory (CSRI).⁵⁷ The CSRI has been widely used in research to examine the cost of chronic pain,^{5–58–60} and has been shown to be a valid measure of frequency of health service use.⁶¹ Medication use is likely to vary throughout the trial duration. As a result, change in medication use (including prescribed and over-the-counter medications) will be measured in post-treatment analysis.

Statistical analysis

A sample size of 63 per group (total=126) will have 80% power, at the 5% significance level, to detect a minimum clinically significant difference in mean improvement on the interference scale score of the BPI of 1 unit (SD of improvement of 2 units) compared to the controls based on a two-sample *t* test. These estimates were derived from the IMMPACT consensus statement regarding the minimum clinically significant change.³⁹ A recent internet-delivered ACT intervention, similar in design and content of the current proposed intervention, demonstrated 20% attrition between allocation and 6-month follow-up.²² Therefore, in line with this anticipated rate of attrition, 152 people with chronic pain will be recruited. The study will be analysed using the principles of intention-to-treat analysis. Suitable graphical (eg, box plots, labelled scatter-plots and case profile plots) and numerical summaries (means, medians, SDs and

quartiles) will be provided for all variables at baseline and for corresponding change scores. As the primary outcome measure, BPI, is measured on an 11-point scale, it will be treated as a continuous variable. The change in the primary response over time (baseline vs postintervention vs 3-month follow-up) will be analysed using a linear mixed model adjusting for baseline, treatment group and within-subject correlation while further adjusting for demographic and clinical explanatory variables as necessary. Model selection will be based on the Akaike Information Criterion⁶² and the underlying assumption through suitable plots of the residuals. A similar approach will be used when analysing the change in those secondary outcome measures recorded on a continuous scale while a non-linear mixed model will be used to compare the changes in the proportions of the ordinal PGIC variable. The sensitivity of the final results to missing data will be investigated using multiple imputation analysis based on chained equations and predictive mean matching.⁶³ All analyses will be completed using a combination of Minitab 16, IBM SPSS V.20 and R (3.02) statistics packages. Each hypothesis will be tested using a two-tailed analysis at the $\alpha=0.05$ level of significance.

Qualitative evaluation

Qualitative evaluation of the internet-delivered ACT programme will be achieved by inviting participants who have completed the intervention to take part in Participative Research Process (PRP)^{64 65} workshops to explore their views on the effectiveness and acceptability of the intervention. The PRP facilitates participants to generate, collate and present their ideas, based on their experience of the internet-delivered ACT intervention. During the PRP workshops, participants will discuss the different elements of the online ACT intervention and explore, through the creation of a Web of Ideas,⁶⁶ if and how the intervention was an effective way to improve the lives of people with chronic pain.

Economic evaluation

An incremental cost-effectiveness analysis will be conducted to compare the costs and outcomes of the ACT intervention compared to the control group. Health benefits will be assessed using the disease-specific clinical effectiveness health measures. Cost-utility analysis will also be conducted using the EQ-5D to assess improvements in HRQOL. In terms of estimating costs, we will include costs falling on the health and social care sector including medication use using data collected as part of the CSRI. Once we have information on the quantity of use, we will translate these into costs using unit cost data available for Ireland for each of the services/products. In the case of hospital costs, resource use will be recorded using diagnosis-related group unit costs. Primary healthcare costs will be calculated using medical card capitation rates and the average charge for non-medical card holders.⁵⁶ We will also record non-medical costs related to out-of-pocket expenses incurred by the person with

chronic pain and their family. These will include expenditure on any treatment not paid by the state, the costs of travelling to, and wait times at, the various healthcare services. We will also record the opportunity cost of work by gathering information on the costs associated with taking time off work or reduced employment for the person with chronic pain or for family members who care for the person with chronic pain. To determine these costs, information on wages will be collected where possible to value these costs. If this is not available, other information such as income, marital status, age and education will be used to provide a proxy for the wage. Uncertainty in the analysis will be explored using a combination of univariate and multivariate analyses, and decision uncertainty will be addressed using cost-effectiveness acceptability curves.⁵⁶

DATA MONITORING AND MANAGEMENT

This trial does not have a data and monitoring committee for the following reasons: the study is minimal risk, chronic pain is a non-life-threatening condition, and the nature of the study population (adult, not considered vulnerable).

All study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access, or on encrypted electronic devices, as appropriate. All records that contain names or other personal identifiers will be stored separately from study records identified by code number. All local and online databases will be secured with password-protected access systems. Paper-based documents that link participant ID numbers to other identifying information will be stored in a separate locked file in an area with limited access. Data stored on computer databases will be password-protected and access to files will be limited to research staff who require direct access. The trial statistician will work on depersonalised data where the participant's identifying information will be replaced by an unrelated sequence of characters. All principal investigators and post-doctoral researchers involved in the running of the trial will be given access to the cleaned data sets. All data sets will be password protected. To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information.

DISSEMINATION

Regardless of the significance, direction or magnitude of effect, the trial findings will be submitted for publication in peer-reviewed journals. Trial findings will also be disseminated through conference abstracts. Once all of the data have been collected and cleaned, we will aim to submit the trial results for publication within 3 months.

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Contributors SH was involved in the design of the intervention and also drafted the manuscript. ED and CO were involved in the economic evaluation of the trial and contributed to the editing of the manuscript. SO was involved in the qualitative evaluation of the trial and contributed to the editing of the manuscript. JN oversaw the statistical aspects of the trial and contributed to the editing of the manuscript. MH contributed not only to the design of the intervention but also to the editing of the manuscript. PM, AWM, TK and SNG contributed to the design of this study and to the editing of the manuscript. BEM contributed to the design of the intervention, supervised the study and also contributed to the editing of the manuscript.

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